IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

JOSEPH S. AUTERI, M.D., Plaintiff, v. VIA AFFILIATES d/b/a DOYLESTOWN HEALTH PHYSICIANS, Defendant.	:	CIVIL ACTION NO. 2:22-cv-03384

ORDER

AND NOW this ___ day of _____, 202__, upon consideration of the Motion for of Defendant, VIA Affiliates d/b/a Doylestown Health, to Exclude the Report and Testimony of Dr. Peter McCullough, and all documents submitted in support thereof and in opposition thereto, it is ORDERED that the Motion is GRANTED. The expert report and opinions of Dr. Peter McCullough shall be EXCLUDED and STRICKEN from the record, and Dr. McCullough shall not be permitted to offer any expert testimony in this matter.

BY THE COURT:

_____

R. BARCLAY SURRICK, J.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

JOSEPH S. AUTERI, M.D., Plaintiff, v. VIA AFFILIATES d/b/a DOYLESTOWN HEALTH PHYSICIANS, Defendant.	CIVIL ACTION NO. 2:22-cv-03384

DEFENDANT'S MOTION TO EXCLUDE THE REPORT AND TESTIMONY OF DR. PETER MCCULLOUGH

Defendant, VIA Affiliates d/b/a Doylestown Health Physicians, hereby moves pursuant to Federal Rule of Evidence 702 to exclude the report and testimony of Dr. Peter McCullough. The basis for this Motion is set forth in the attached Memorandum of Law, which is incorporated herein.

Respectfully submitted,

/s/ Christopher D. Durham

Christopher D. Durham, Esquire
Adam D. Brown, Esquire
Elisabeth G. Bassani, Esquire
Duane Morris LLP
30 South 17th Street
Philadelphia, PA 19103
(215) 979-1800

Attorneys for Defendant, VIA Affiliates d/b/a Doylestown Health Physicians

Dated: May 12, 2025

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FOR THE EASTERN DISTRICT OF PENNSYLVANIA

JOSEPH S. AUTERI, M.D., Plaintiff, v. VIA AFFILIATES d/b/a DOYLESTOWN HEALTH PHYSICIANS, Defendant.	:	CIVIL ACTION NO. 2:22-cv-03384

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT'S MOTION TO EXCLUDE THE REPORT AND TESTIMONY OF DR. PETER MCCULLOUGH

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I. INTRODUCTION

Plaintiff, Dr. Joseph Auteri, is a heart surgeon and former employee of Defendant, VIA Affiliates d/b/a Doylestown Health Physicians ("Doylestown Health"). Plaintiff's employment with Doylestown Health ended in November 2021, during the COVID-19 pandemic, after he failed to comply with a Doylestown Health requirement that he become vaccinated for COVID-19 (the "Mandate"). In this action, Plaintiff contends that Doylestown Health unlawfully did not accommodate his religious belief, which he claims required an exemption from the Mandate.

In support of his religious discrimination claims, Plaintiff has proffered the opinions of purported expert Dr. Peter McCullough. The Court should exclude these opinions for the following reasons.

First, Dr. McCullough has no relevant education, training, expertise, knowledge, or experience regarding COVID-19, and a history of spreading false information about COVID-19. For this reason alone, the Court should not allow any presentation of his opinions in this case, in any form.

Second, Dr. McCullough's opinions are factually groundless. He attempts to bolster his conclusions by misconstruing or mispresenting sources, repeating debunked falsehoods, and ignoring key facts. His opinions therefore do not meet the legal standard for reliability that is required of an expert witness.

Third, Dr. McCullough's opinions do not fit the facts of this case. His purported views about alleged genetic alteration and transmissibility by vaccinated persons are irrelevant and could not help a factfinder determine any fact in issue.

For these reasons, as discussed in greater detail below, the Court should exclude Dr. McCullough's report from the record and preclude him from testifying at any trial in this case.

II. BACKGROUND

At issue in this case is whether Doylestown Health should have accommodated Plaintiff's alleged religious belief(s) by exempting him from the Mandate, implemented in 2021 during the COVID-19 pandemic. Pl.'s 2d Am. Compl., ECF Doc. No. 20. Plaintiff contends that Doylestown Health violated his rights by not doing so. *Id.* Doylestown Health contends that Plaintiff's objections to the vaccine were not religious as a matter of law and that, in any event, it could not grant Plaintiff an exemption without undue hardship. *See Groff v. DeJoy*, 600 U.S. 447, 453–54 (2023) (holding Title VII of the Civil Rights Act of 1964 "requires employers to accommodate the religious practice [or belief] of their employees unless doing so would impose an 'undue hardship on the conduct of the employer's business.'") (quoting 42 U.S.C. § 2000e(j).

One of Plaintiff's purported objections to the COVID-19 vaccines is based on his stated belief that such vaccines were developed using messenger ribonucleic acid ("mRNA") technology and that they alter people's deoxyribonucleic acid ("DNA"). As he testified, he believes mRNA vaccines, "by definition, alter DNA and RNA in the recipient, and that goes against my deeply-held religious conviction." Exhibit A, Excerpts from Deposition of Plaintiff, 440:7-441:7. He further explained:

> It was an mRNA vaccine, which is not an attenuated virus, or small amounts of virus. The vaccine label -- the vaccine definition changed, and it became outside of where I was comfortable when they're trying to change my DNA. . . . I don't believe that's consistent with my religious belief that we shouldn't mess with people's DNA.

Ex. A, Pl. Dep. Tr. 313:12-315:3.

In connection with his request for a religious exemption from the Mandate, Plaintiff proposed limited alternative precautionary measures: (1) a daily health questionnaire, including temperature checks; and (2) weekly COVID-19 testing. Exhibit B, Letter dated October 22,

2021, from Kimberly L. Russell to Barbara Hebel, D0000201-0000207. Doylestown Health informed Plaintiff that it could not grant his requested exemption because it would have caused an undue hardship by endangering the health and safety of its patients and staff. Exhibit C, Letter dated November 9, 2021, from Christopher Durham to Kimberly L. Russell, D0000824-33.

In support of his theories, Plaintiff proffers the opinions set forth in the report of Dr. Peter McCullough. Exhibit D, Expert Report of Dr. Peter A. McCullough, MD, MPH (the "McCullough Report"). Dr. McCullough states that he is an internist and cardiologist. Ex. D, McCullough Report, at 2. He represents that he is qualified as an expert based primarily on his own publications and public statements, including "a series of OPED's" and "numerous public political appearances addressing pandemic issues[.]" *Id.* He also says he treats patients for illnesses related to COVID-19, which, of course, a wide range of medical providers have done over the past five-plus years and continue to do. *Id.* at 3.

The McCullough Report presents two opinions that Plaintiff seeks to have Mr. McCullough express as an expert witness in this matter. First, Dr. McCullough opines, with citation to Food and Drug Administration ("FDA") regulatory guidance, that "the COVID-19 vaccine(s) offered at the time of [Plaintiff's] termination in November 2021 are gene therapy products which have the ability to alter an individual's genome, and [Plaintiff's] expressed religious concern about those vaccines was supported by the data available at the time." Ex. D, McCullough Report, at 6. Second, Dr. McCullough opines that Plaintiff "presented no increased safety risk to . . . Doylestown Health's patients or staff and that [his] proposed reasonable accommodation of weekly testing and daily health screenings provided better safety protection than Doylestown Health's reliance upon the COVID-19 vaccines[.]" *Id.* Laying bare that the

McCullough Report is nothing more than an advocacy piece, much like his op-eds and cable news television appearances, Dr. McCullough purports to reach a legal conclusion based on these opinions that Plaintiff's "termination based upon his refusal to get vaccinated because of sincerely held religious beliefs was unlawful." *Id.* at 19.

Doylestown Health intends to present at trial (if necessary) testimony from Dr. Daniel Salmon, as outlined in his written report. Exhibit E, Expert Report of Dr. Daniel Salmon, Ph.D., MPH (the "Salmon Report"). Dr. Salmon is a vaccinologist at the Johns Hopkins University Bloomberg School of Public Health. *Id.* at 1, 21. He serves as a Professor of Global Disease Epidemiology and Control in the Johns Hopkins University Department of International Health, with a joint appointment in the Department of Health, Behavior and Society. *Id.* Among Dr. Salmon's opinions are that: (1) it was widely accepted in the scientific community in November 2021 that COVID-19 vaccines are not "gene therapy products," because scientific evidence did not support such an assertion, *id.* at 11; and (2) based on the information known to healthcare facilities in November 2021, the precautions Plaintiff proposed in lieu of COVID-19 vaccination were inadequate to address the risks of COVID-19 to the health and safety of Doylestown Health's patients and staff, *id.* at 16-17.

Dr. Salmon also notes that the Janssen Biotech COVID-19 vaccine (also referred to as the "J&J vaccine"), available in 2021, was not an mRNA vaccine. *Id.* at 11. Receiving that vaccine complied with the Mandate. Exhibit F, Email dated August 30, 2021, from Barbara Hebel to associates, D0001587-88, at D0001587 ("If receiving the J&J vaccine, Associates may schedule anytime up until October 4, 2021.").

III. LEGAL STANDARD

The admissibility of expert testimony is governed by Federal Rule of Evidence 702, which provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training or education may testimony in the form of an opinion or otherwise if:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principals and methods; and
>
> (d) the expert has reliably applied the principals and methods to the facts of the case.

Fed. R. Evid. 702. Trial courts are to function as "gatekeepers" with respect to the admission of expert evidence pursuant to Rule 702. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993). In performing this role, a trial court ensures "that any and all expert testimony or evidence is not only relevant but also reliable." *Kannankeril v. Terminix Int'l*, 128 F.3d 802, 805 (3d Cir. 1997) (citing *Daubert*, 509 U.S. at 589).

Rule 702 contains a "trilogy" of requirements: "qualification, reliability and fit." *Estate of Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003). The party offering the expert has the burden of establishing by a preponderance of the evidence that the proffered expert meets these requirements. *Padillas v. Stork-Gamco, Inc.*, 186 F.3d 412, 418 (3d Cir. 1999); *Daubert*, 509 U.S. at 592, n. 10.

"Qualification refers to the requirement that the witness possess specialized expertise." *Estate of Schneider*, 320 F.3d at 404. The reliability element requires that the testimony "be based on the methods and procedures of science rather than on subjective belief or unsupported speculation; and the expert must have good grounds for his or her opinion." *Id.* (internal

quotation marks and citation omitted). To satisfy the fit requirement, "testimony must be relevant for the purposes of the case and must assist the trier of fact." *Id.*

IV. LEGAL ARGUMENT

A. Dr. McCullough is Not Qualified to Provide Opinions Regarding COVID-19, the COVID-19 Vaccines, or Related Topics.

"In order to be deemed qualified, a proffered expert must possess the necessary skills, knowledge, education, experience, and training to express an expert opinion." *Slattery v. Main Line Health, Inc*., No. CV 22-4994, 2025 WL 897526, at *3 (E.D. Pa. Mar. 24, 2025). Dr. McCullough, who has no relevant experience or training and is well-known to be a purveyor of misinformation to the public, possesses none of these attributes, which led the *Slattery* court to "conclude[ ] that Dr. McCullough is not qualified to give opinions related to COVID-19, the COVID-19 vaccine, or the public health response to COVID-19[.]" *Id.* at *7. Plaintiff's attempt to present Dr. McCullough as an expert on substantially similar subject matter in this case demands the same result: exclusion of his opinions for lack of qualification. *See id.* (finding Dr. McCullough unqualified and "strik[ing] his . . . report from the record").

Dr. McCullough is an internist and cardiologist with no expertise in vaccinology or epidemiology whose "practice was almost entirely internal medicine and clinical cardiology until he began publishing on COVID-19 in the early days of the pandemic." *Navy SEAL 1 v. Austin*, 600 F. Supp. 3d 1, 16 (D.D.C. 2022), *vacated and remanded on other grounds*, No. 22-5114, 2023 WL 2482927 (D.C. Cir. Mar. 10, 2023). This lack of relevant expertise or experience, standing alone, disqualifies Dr. McCullough from providing expert opinions regarding COVID-19 and related matters.

In *Slattery*, which—like this case—was about a doctor's religion-based challenge to a hospital's COVID-19 vaccination mandate, the court reasoned:

> Not only has Dr. McCullough never *practiced* in the field of epidemiology, but his presence in this field did not begin until the COVID-19 pandemic began in early 2020. The Court is unwilling to certify an expert on a relatively novel virus when they have had no previous experience with epidemiology, immunology, or infectious disease.

Id. at *7 (emphasis in original). The *Slattery* court had an additional "concern" about Dr. McCullough's qualifications to provide expert testimony regarding COVID-19 vaccines and related matters: "Dr. McCullough has previously had a preliminary injunction issued against him for making false statements, specifically claiming that he was affiliated with Baylor University after he was fired for spreading medical, COVID-related misinformation." *Slattery*, 2025 WL 897526, at *7 (citing *Navy Seal I*, 600 F. Supp. 3d at 16) (identifying preliminary injunction for false statements as "a fact and concern that has been noted by a fellow District Court").[1] This history of false public statements, together with the other deficiencies in Dr. McCullough's qualifications and opinions, caused the *Slattery* court to find him unqualified to provide expert testimony on COVID-19. *Id.* at *7-*9.

Slattery is far from an outlier decision in finding Dr. McCullough unqualified to opine on COVID-19. As another district court observed, "[n]ot only is it doubtful that Dr. McCullough's credentials demonstrate he is an expert on COVID-19, Dr. McCullough makes several claims that are outside the conclusions of the mainstream of the vast scientific studies of the COVID-19 virus and COVID-19 vaccination." *Roth v. Austin*, 603 F. Supp. 3d 741, 774 (D. Neb. 2022). Thus, "Dr. McCullough is hardly a 'real expert' in the field," as he claims. *Id.*; *see Slattery*, 2025 WL 897526, at *7 (citing *Roth* and *Navy Seal I*) ("This Court is not alone in being skeptical

[1] The *Navy Seal I* court found this fact "problematic[ ]" for purposes of deciding whether to accept Dr. McCullough's opinions in that matter, which were "outside the scientific mainstream[.]" *Navy Seal I*, 600 F. Supp. 3d at 17.

about Dr. McCullough."); *Navy Seal I*, 600 F. Supp. 3d at 16 (noting that "a battery of medical authorities contest Dr. McCullough's positions").

Furthermore, Dr. McCullough's qualifications are lacking on an even more basic level. In 2022, the American Board of Internal Medicine ("ABIM") revoked his board certifications for making false public statements about COVID-19 vaccines.[2] Exhibit G, October 18, 2022 letter from ABIM to Dr. McCullough. In its letter notifying Dr. McCullough of its revocation decision, the ABIM stated:

> [Y]ou have provided false or inaccurate medical information to the public. By casting doubt on the efficacy of COVID-19 vaccines with such seemingly authoritative statements, made in various official forums and widely reported in various media, your statements pose serious concerns for patient safety. Moreover, they are inimical to the ethics and professionalism standards for board certification.

Id. at 1. The ABIM noted, in particular, Dr. McCullough's testimony before a Texas legislative committee, an appearance on Fox News, and other public appearances and statements in which he asserted views about COVID-19 vaccines that were contrary to accepted science. *Id.*

Dr. McCullough's lack of any relevant knowledge, expertise, or experience, his history of spreading misinformation regarding COVID-19, and the revocation of his board certification by ABIM all demonstrate that he is not qualified to provide expert opinions on any of the issues in

[2] In his report, Dr. McCullough asserts, "I am board certified by the National Board of American Physicians and Surgeons [('NBAPS')] in internal medicine and cardiovascular diseases." *Id.* at 2. The American Board of Medical Specialties ("ABMS"), of which ABIM is a Member Board, has publicly criticized the NBAPS for its lack of any "process for defining specialty specific standards for knowledge" and its failure to "offer an external assessment of knowledge and skills." ABMS, *The ABMS Response to National Board of Physicians and Surgeons' Assertion of Certifying Body Equivalency* (July 29, 2022), https://www.abms.org/newsroom/abms-response-to-nbpas-assertion-of-certifying-body-equivalency/ (last visited May 12, 2025). The ABMS has stated that it "strongly disagrees with the persistent and misleading assertions that the [NBPAS] recertification process provides a means of continuing ABMS board certification or is equivalent to ABMS board certification." As the ABMS has further explained, "[c]laims of equivalence to ABMS certification or that NBPAS is a means to maintain ABMS Member Board certification are misleading to the profession, and most importantly, to the public who depend upon the strength of ABMS board certification." *Id.*

this matter. Accordingly, the Court should strike his expert report from the record and preclude Plaintiff from relying on his opinions in summary judgment proceedings or at trial.

B. Dr. McCullough's Opinions Are Not Reliable.

The reliability prong of the *Daubert* analysis requires that experts ground their opinions in adequate knowledge and data. "An expert's opinion is reliable if it is 'based on the methods and procedures of science' rather than on 'subjective belief or unsupported speculation;' the expert must have 'good grounds' for his or her belief." *Elcock v. Kmart Corp.*, 233 F.3d 734, 745 (3d Cir. 2000) (quoting *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 (3d Cir. 1994)). "[A]ny step [in an expert's analysis] that renders the analysis unreliable under the *Daubert* factors renders the expert's testimony inadmissible. This is true whether the step completely changes a reliable methodology or merely misapplies that methodology." *In re Paoli R.R. Yard Litig.*, 35 F.3d at 745. In applying this standard, "[t]he Court must exercise its gatekeeping function to prevent a fact finder from hearing blatantly wrong and unreliable statements of purported science." *Slattery*, 2025 WL 897526, at *9.

Here, as in *Slattery*, in which the court struck Dr. McCullough's report from the summary judgment record and precluded him from testifying at any trial due in part to the unreliability of his opinions, "Dr. McCullough's expert report is simply a resuscitation of a few hand-picked articles which are contrary to CDC and FDA guidance available at the time in question." *Slattery*, 2025 WL 897526, at *9. As he did in *Slattery*, "Dr. McCullough repeatedly makes grand and conclusory assertions that are unsupported by studies or are outright incorrect." *Id.* This Court should follow the reasoning of *Slattery* and reach the same conclusion: that Dr. McCullough's report "is based on unreliable principles, methods, and information and, therefore, must be excluded." *Id.*

1. Dr. McCullough's Opinions Regarding Alleged Genetic Alteration Are Scientifically Unfounded.

Dr. McCullough asserts that "the available Emergency Use Authorized vaccines (Pfizer, Moderna, Janssen) were in essence genetic biotechnology products which have been shown to alter the human genome by reverse transcription." McCullough Report at 7-8.[3] He claims, therefore, that all COVID-19 vaccines "are classified as gene delivery therapies and should be under a 15-year [FDA] regulatory cycle[.]" *Id.* at 7. He posits that "FDA regulatory guidance" supports this claim. *Id.*

As a threshold matter, Dr. McCullough's core assertion that COVID-19 vaccines are "genetic biotechnology products" is supported by nothing other than his own purported belief. The "FDA regulatory guidance" he cites does not address COVID-19 vaccines at all, let alone establish that they "are classified as gene delivery therapies." In fact, it explicitly states: "This guidance *does not apply to vaccines for infectious disease indications*[.]" FDA, *Long Term Follow-Up After Administration of Human Gene Therapy Products Guidance for Industry* (January 2020), at n.3 (emphasis added) https://www.fda.gov/media/113768/download (last visited May 12, 2025).[4]

Furthermore, these opinions have been scientifically debunked as untrue. The FDA has not said that any COVID-19 vaccine alters one's genetic makeup. The FDA instead has stated *the opposite*, making clear in a statement regarding its full approval of the COVID-19 vaccine

[3] As support for this claim, Dr. McCullough cites an article regarding the COVID-19 vaccine developed and manufactured by Pfizer and BioNTech, which does not address either of the other two vaccines available in November 2021, those developed and manufactured by Moderna and Janssen Biotech. *Id.* at n.25.

[4] Notably, the FDA issued the guidance in January 2020, before development of any of COVID-19 vaccines had begun. Therefore, Dr. McCullough's citation to the FDA's guidance for his claim that the COVID-19 vaccines "are classified as" products that are covered by that guidance is, at best, misleading.

developed and manufactured by Pfizer and BioNTech, that "[t]he mRNA in [the vaccine] is only present in the body for a short time and is not incorporated into - nor does it alter - an individual's genetic material." FDA, *FDA Approves First COVID-19 Vaccine* (Aug. 23, 2021), https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine (last visited May 12, 2025). Thus, it is not the case, as Dr. McCullough implies, that the FDA somehow has endorsed his fringe, discredited view about alleged genetic effects of the vaccine.

The CDC also has recognized, contrary to Dr. McCullough's opinion, that COVID-19 vaccines using mRNA technology, such as the Moderna and Pfizer/BioNTech vaccines, do not alter one's DNA, stating that "COVID-19 vaccines do not change or interact with your DNA in any way." CDC, *Myths and Facts about COVID-19 Vaccines* (last updated Feb. 16, 2023), https://archive.cdc.gov/www_cdc_gov/coronavirus/2019-ncov/vaccines/facts.html (last visited May 12, 2025) (bold text in original). As Dr. Salmon explains, mRNA COVID-19 vaccines cannot change a person's genetic makeup by altering DNA. Ex. E, Salmon Report, at 11. Similarly, the National Human Genome Research Institute of the National Institutes of Health has stated that "mRNA vaccines are safe and cannot alter your DNA." *Id.*[5] It was widely accepted among the scientific community in November 2021 that mRNA vaccines could not alter one's DNA. *Id.*

Courts in the Third Circuit also have recognized that claims of genetic alteration resulting from COVID-19 vaccines, like Dr. McCullough's opinions here, are not accurate, specifically rejecting attempts by plaintiffs to "re-categoriz[e] the COVID-19 vaccines as 'Gene Therapy

[5] Dr. Salmon cites NATIONAL HUMAN GENOME RESEARCH INSTITUTE OF THE NATIONAL INSTITUTE OF HEALTH, *Fact Sheet: Understanding COVID-19 mRNA Vaccines*, https://www.genome.gov/about-genomics/fact-sheets/Understanding-COVID-19-mRNA-Vaccines (last visited May 12, 2025).

Products.'" *See*, *e.g.*, *Messina v. Coll. of N. J.*, 566 F. Supp. 3d 236, 248-49 (D.N.J. 2021) (denying request for injunction against COVID-19 vaccine mandate in part because plaintiffs were not likely to succeed on merits of argument that COVID-19 vaccines were genetic therapy); *Smith v. Biden*, No. 1:21-CV-19457, 2021 WL 5195688, at *6 (D.N.J. Nov. 8, 2021) (holding that plaintiffs "provided no medical authority or competent evidence to support the argument that COVID-19 vaccines are gene therapy products rather than vaccines").[6] This Court may take judicial notice of the fact that "[t]he vaccine does not alter a person's DNA." *Brunson v. Aiken/Barnwell Ctys. Cmty. Action Agency, Inc.*, No. CV 1:24-36-JDA-SVH, 2024 WL 4186082, at *10 n.3 (D.S.C. Mar. 1, 2024), *report and recommendation adopted*, No. 1:24-CV-00036-JDA, 2024 WL 3665783 (D.S.C. Aug. 6, 2024) (taking "judicial notice of factual information" posted on CDC website directly contradicting plaintiff's purported belief that COVID-19 vaccines alter DNA).

An "expert's testimony must be accompanied by a sufficient factual foundation before it can be submitted to the jury." *Gumbs v. Int'l Harvester, Inc.*, 718 F.2d 88 (3d Cir. 1983). Dr. McCullough's claim that COVID-19 vaccines are "gene therapy products" that can alter one's genetic makeup fails this test wholesale; there is no factual foundation for such a theory. Because these purported opinions are contrary to scientific methods and procedures and are instead based on subjective belief and unsupported speculation, they are not reliable under *Daubert*. *Estate of Schneider*, 320 F.3d at 404. The Court should exclude these opinions.

[6] *See also Valdez v. Lujan Grisham*, No. 21-CV-783 MV/JHR, 2022 WL 3577112, at *12–13 (D.N.M. Aug. 19, 2022) ("Plaintiffs characterize the COVID-19 vaccines as 'gene modification therapies,' . . . but provide no medical authority to distinguish the COVID-19 mRNA vaccines from any other vaccines; indeed, public health information is to the contrary, as 'the CDC has clearly opined that the [vaccines against COVID19] constitute 'vaccines'").

2. Dr. McCullough's Opinions Regarding Transmission of COVID-19 by Vaccinated Individuals Are Based on Incomplete and Misleading Information.

Dr. McCullough further opines that "an unvaccinated Dr. Autieri [sic] posed no undue or additional risk or harm to himself, hospital staff, or patients greater than that posed by Doylestown Health's vaccinated medical staff." Ex. D, McCullough Report, at 13. Dr. McCullough's rationale for this opinion is that "COVID-19 vaccinated staff members could transmit the virus" and, therefore, he concludes, "Doylestown Health's reliance upon the COVID-19 vaccines to determine 'patient safety' likely made the spread of the virus worse" rather than limiting it. *Id.* He further draws the sweeping conclusion that, "[b]y the time of Dr. Auteri's termination on November 18, 2021, the COVID-19 vaccine campaign had failed and the vaccine status was irrelevant for surgeons such as Dr. Auteri." *Id.* at 17. These views lack scientific grounds.

Dr. McCullough cites various publications that he claims support these theories but, in fact, he "misconstrues the [sources] upon which [he] relies." *Divine Equal. Righteous v. Overbrook Sch. for Blind*, No. CV 23-846, 2025 WL 511054, at *3 (E.D. Pa. Feb. 14, 2025); Ex. D, McCullough Report, at 9 n.36-41. For example, Dr. McCullough misleadingly cites to an abstract of an article from *The Lancet* regarding transmission among the vaccinated, presenting it as one of "[m]ultiple studies [that] indicated fully vaccinated individuals were carrying large viral loads of SARS-CoV-2 in the nasopharynx and fully capable of spreading the virus to vaccinated or unvaccinated contacts." *Id.* at 9, n.37. Like the proffered expert in *Divine Equality Righteous*, Dr. McCullough relies on this source for his opinion "regarding transmission." *Divine Equal. Righteous*, 2025 WL 511054, at *3. A relevant portion of the

abstract[7] of the *Lancet* article, however, makes clear that Dr. McCullough is cherry-picking the article's findings:

> ***Vaccination reduces the risk of the delta variant infection and accelerates viral clearance.*** Nonetheless, fully vaccinated individuals with breakthrough infections have peak viral load similar to unvaccinated cases and can efficiently transmit infection in a household setting, including to fully vaccinated contacts.[8]

The McCullough Report ignores the first sentence of this passage, which undermines his purported opinion.

Based in part on the *Lancet* article, Dr. McCullough opines that, because COVID-19 "appeared in fully vaccinated persons and was able to spread among" vaccinated individuals, "mass vaccination was at best worthless." Ex. D, McCullough Report, at 10-11. "But as another court put it in evaluating the same argument, regarding the same *Lancet* [a]rticle . . . 'That's a half-truth.'" *Divine Equal. Righteous*, 2025 WL 511054, at *3 (quoting *Federoff v. Geisinger Clinic*, 571 F. Supp. 3d 376, 389 (M.D. Pa. 2021)). The *Federoff* court correctly noted:

> While vaccinated individuals that catch COVID-19 may be as likely to infect others, ***they are significantly less likely to be infected in the first place***—as the authors emphasized ibn their opening sentence: "Vaccination reduces the risk of delta variant infection ...." ***A recent CDC study estimated that vaccinated individuals are three-times less likely to be infected***. And both the CDC and The Lancet studies suggest that this number could be increased through an immunity enhancing booster shot.

[7] Singanayagam A, Hakki S, Dunning J, Madon KJ, Crone MA, Koycheva A, Derqui-Fernandez N, Barnett JL, Whitfield MG, Varro R, Charlett A, Kundu R, Fenn J, Cutajar J, Quinn V, Conibear E, Barclay W, Freemont PS, Taylor GP, Ahmad S, Zambon M, Ferguson NM, Lalvani A; *ATACCC Study Investigators. Community transmission and viral load kinetics of the SARS-CoV-2 delta (B.1.617.2) variant in vaccinated and unvaccinated individuals in the UK: a prospective, longitudinal, cohort study*. Lancet Infect Dis. 2022 Feb;22(2):183-195. doi: 10.1016/S1473-3099(21)00648-4. Epub 2021 Oct 29. Erratum in: Lancet Infect Dis. 2021 Dec;21(12):e363. doi: 10.1016/S1473-3099(21)00701-5. PMID: 34756186; PMCID: PMC8554486. https://pubmed.ncbi.nlm.nih.gov/34756186/.

[8] *Id.* (emphasis added).

571 F. Supp. 3d at 389-90 (emphasis added). And the *Divine Equality Righteous* court determined that the plaintiff's expert's "misconstruction of the [sources] cited in his report," including the same *Lancet* article on which Dr. McCullough erroneously relies here, "undermine[s] his reliability as it pertains to vaccine efficacy." 2025 WL 511054, at *3.[9]

The *Lancet* article[10] further disproves Dr. McCullough's stated theory that vaccination was ineffective because of transmissibility, in that it "explicitly recommends '[i]ncreasing population immunity *via booster programmes and vaccination*' and concludes that '[this] analysis suggests that direct protection of individuals at risk of severe outcomes, *via vaccination* and non-pharmacological interventions, will remain central to containing the burden of disease caused by the delta variant.'" *Cline v. PeaceHealth*, No. 6:23-CV-01985-MTK, 2025 WL 295113, at *5 (D. Or. Jan. 24, 2025) (modification in original) (emphasis added) (quoting *Lancet* article). Rejecting a similar mischaracterization of the *Lancet* article by a proffered expert, the *Cline* court determined that the proffered expert's opinion—similar to Dr. McCullough's here—that transmissibility by vaccinated persons meant that vaccination was in fact *increasing* the spread of COVID-19 "directly contradicts the scientific research it relies on" and that the expert's interpretation of the *Lancet* article and other sources thus was "at best incompetent, and at worst, dishonest." *Cline*, 2025 WL 295113, at *5.

[9] Dr. McCullough has similarly mischaracterized or exaggerated the significance of sources in other cases, and courts have correctly rejected his opinions in different contexts for that reason. *See Harris v. Univ. of Mass., Lowell*, 557 F. Supp. 3d 304, 309 n.5 (D. Mass. 2021), *appeal dismissed*, 43 F.4th 187 (1st Cir. 2022) (explaining that Dr. McCullough's attempt to "dispute[ ] the safety and efficacy of the vaccines" was based on flawed data and mischaracterizations); *Klaassen v. Trs. of Indiana Univ.*, 549 F. Supp. 3d 836, 878 (N.D. Ind. 2021), *vacated and remanded on other grounds*, 24 F.4th 638 (7th Cir. 2022) (noting that "[a] close review of Dr. McCullough's testimony reveals a true failing" regarding attempts to link reported side effects to vaccine).

[10] The full text of the article is available at https://doi.org/10.1016/S1473-3099(21)00648-4.

Dr. McCullough's opinion that exempting Plaintiff from the Mandate would not have increased health and safety risks to Doylestown Health's patients and staff is based entirely on the "half-truth" that Plaintiff could have transmitted the virus despite being vaccinated. Ex. D, McCullough Report, at 11; *Divine Equal. Righteous*, 2025 WL 511054, at *3. The sources he cites for this opinion support *only* that "half-truth"; they discuss transmissibility notwithstanding vaccination, but they *do not* support a conclusion that vaccination was, as Dr. McCullough claims, "at best worthless."[11] Ex. D, McCullough Report, at 10-11. Dr. McCullough's misconstruction of sources in this regard ignores the critical fact, *acknowledged in one of the very sources on which he relies*, that "[v]accination reduces the risk of . . . infection." *Cline*, 2025 WL 295113, at *4.

By disregarding this key fact, Dr. McCullough offers a wholly unreliable opinion, not based on the "methods and procedures of science," *Daubert*, 509 U.S. at 590, that, "by the time of [Plaintiff's] termination . . . the COVID-19 vaccine campaign had failed and . . . vaccine status was irrelevant for surgeons such as [Plaintiff]." Ex. D, McCullough Report, at 17. Because Dr. McCullough does not have "good grounds" for his opinion in this regard, *In re Paoli R.R. Yard Litig.*, 35 F.3d at 743, the Court should exclude it.

[11] In addition, Dr. McCullough's opinion about transmission of COVID-19 by those who are vaccinated is unreliable because it is based almost entirely on sources published later than November 2021, *after* Doylestown Health terminated Plaintiff's employment for not complying with the Mandate. Ex. D, McCullough Report, at 9 n.37-41, 44, 49. The data on which those sources relied was not available in 2021 and could not have informed any decision-making when all events relevant to this litigation occurred. Therefore, they cannot support Dr. McCullough's opinions about the events at issue in this case.

C. Dr. McCullough's Opinions Do Not Fit This Case Because They Would Not Assist a Trier of Fact to Understand the Evidence or Determine Any Fact in Issue.

An expert's testimony satisfies the fitness prong of the Daubert standard only if "it will help the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702(a). Fitness is "essentially a relevance determination," and "an expert's testimony will be excluded if the scientific knowledge presented is not relevant to the determination of the facts in the present case." *Slattery*, 2025 WL 897526, at *4 (citing *Cohen v. Cohen*, 125 F.4th 454, 464 (3d Cir. 2025)); *see also Torain v. City of Philadelphia*, CV 14-1643, 2023 WL 174952, at *3 (E.D. Pa. Jan. 12, 2023) ("Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful.").

Dr. McCullough's opinions do not relate to any issue in this case. His views about alleged genetic effects of COVID-19 vaccines are irrelevant, because: (1) one of the vaccines available to Plaintiff in November 2021 was a conventional viral vector vaccine that did not use mRNA technology and thus did not implicate the genetic concern first raised by Plaintiff in his deposition (Pl. Dep. 314:3-315:22,440:7-441:7); and (2) a factfinder in this matter would have no occasion to decide whether or not COVID-19 vaccines are "gene therapy products," because the relevant question is whether Plaintiff's beliefs are *religious*, not whether his supposed *scientific* understanding of the vaccines is right or wrong.[12] Dr. McCullough's assertion that COVID-19 vaccines did not stop vaccinated persons from transmitting COVID-19 also is irrelevant because it ignores the fact that the vaccines undisputably reduced the likelihood of individuals being

[12] *See Slattery*, 2025 WL 897526, at *5 (finding Dr. McCullough's opinions did not "fit" facts of case because "the Court does not see how a medical doctor is qualified to discuss the religious beliefs of" plaintiff and, "[w]ith all due respect to Dr. McCullough and his knowledge, training and experience as a medical doctor, Dr. McCullough is not an expert in religion").

infected with the virus in the first place, which necessarily would reduce the rate of transmission. These opinions do not meet the "fit" requirement of *Daubert* and, therefore, they should be excluded.[13]

1. Dr. McCullough's Opinions Regarding Alleged Genetic Alteration Have Nothing to Do with Any Issue(s) in This Case.

In addition to being demonstrably incorrect, Dr. McCullough's opinion that all COVID-19 vaccines are "gene therapy products" suffers from another fatal defect: it focuses exclusively on mRNA vaccines, ignoring the fact that the Janssen Biotech vaccine, which was available to Plaintiff in November 2021 and would have enable him to comply with the Mandate, "was *not an mRNA vaccine*." Ex. E, Salmon Report, at 11 (emphasis added); Ex. F. While the Moderna and Pfizer/BioNTech vaccines used mRNA technology, Ex. E, Salmon Report, at 9-11, the Janssen Biotech vaccine was a conventional viral vector vaccine that did not use mRNA technology, *id.* at 11. Therefore, Dr. McCullough's (unfounded and scientifically debunked) opinion that mRNA vaccines somehow alter one's genes would not assist the trier of fact to understand any issue in this case.

In any event, this case is not about whether certain vaccines are "gene therapy products" or some other type of product. Rather, the only relevant question pertaining to Plaintiff's stated belief that vaccines alter DNA is whether that belief was religious, as opposed to scientific. *See Africa v. Com. of Pa.*, 662 F.2d 1025, 1032 (3d Cir. 1981) (setting forth legal standard for

[13] Additionally, Dr. McCullough impermissibly states a legal conclusion that purports to resolve the ultimate dispute in this matter, stating, "[Plaintiff]'s termination based upon his refusal to get vaccinated because of sincerely held religious beliefs was unlawful." Ex. D, McCullough Report, at 19. "While [Federal] Rule [of Evidence] 704 allows experts to provide an opinion about the 'ultimate issue' in a case, it prohibits experts from opining about the ultimate legal conclusion or about the law or legal standards." *Patrick v. Moorman*, 536 F. App'x 255, 258 (3d Cir. 2013). Dr. McCullough's proffer of this legal conclusion therefore is a violation of Rule 704 and another basis for exclusion.

whether belief is religious and thus entitled to protection under applicable civil rights laws); *Hand v. Bayhealth Med. Ctr., Inc.*, No. CV 22-1548-RGA, 2024 WL 359245, at *5 (D. Del. Jan. 31, 2024), *aff'd sub nom. McDowell v. Bayhealth Med. Ctr., Inc.*, No. 24-1157, 2024 WL 4799870 (3d Cir. Nov. 15, 2024) (holding plaintiff's stated belief that mRNA vaccine "will be integrated into your DNA, thus altering the DNA that God created us with" was "based fundamentally on her scientific and medical beliefs about the vaccine," and "[s]uch medical and scientific judgments do not qualify as religious belief"). Dr. McCullough's purported opinion about alleged genetic effects of COVID-19 vaccines has no bearing on this question, because it merely seeks to bolster Plaintiff's (mistaken) scientific or medical understanding of the vaccines, which in turn only serves to demonstrate the areligious nature of that belief.

For these reasons, Dr. McCullough's opinion regarding COVID-19 vaccines as "gene therapy products" is irrelevant and unhelpful. It should be excluded.

2. Dr. McCullough's Opinions Regarding Transmission of COVID-19 by Vaccinated Individuals are Irrelevant to Whether Vaccination Limited COVID-19 Infection.

As discussed above, Dr. McCullough opines that transmission by a vaccinated person is possible and, therefore, vaccination mandates did not stop the spread of COVID-19. Ex. D, McCullough Report, at 9-11, 13-17. This opinion ignores the threshold question a factfinder would need to answer in connection with an undue hardship analysis: whether vaccination reduced the likelihood of *infection in the first place*, which in turn reduced the likelihood of transmission. It therefore does not fit the facts of this case.

Dr. McCullough relies in large part for his opinion about the significance of transmissibility on an August 2021 statement by then-CDC Director Dr. Rochelle Walensky to the effect that data showed similar viral loads in vaccinated and unvaccinated people, so that

transmission could occur notwithstanding vaccination. Ex. D, McCullough Report, at 9. As at least one court has recognized, this statement is irrelevant to the question of whether vaccines prevent COVID-19 infection because it "concerns the viral loads of persons who have already suffered an infection of COVID-19 and *not whether vaccines help prevent infection in the first place*." *Hailey v. Legacy Health*, No. 3:23-cv-00149-IM, 2024 WL 4253238, at *15 (D. Or. Sept. 20, 2024) (emphasis added) (internal quotation marks omitted). Therefore, Dr. McCullough's opinion in this regard would not assist a trier of fact to understand any issue in this case, because whether COVID-19 vaccines prevent transmission by vaccinated individuals who are already infected does not address whether the vaccines prevent those same individuals from becoming infected in the first place, which self-evidently would reduce the likelihood of transmission.

The undue hardship analysis in this case turns on whether "the on-site spread of [COVID-19] compromised [Doylestown Health's] mission and ability to care for sick patients, and . . . jeopardized the health and efficacy of its employees and staff." *Bushra v. Main Line Health, Inc.*, No. 24-1117, 2025 WL 1078135, at *2 (3d Cir. Apr. 10, 2025). The spread of COVID-19 is not merely a function of how easily an infected person can transmit the virus; it is indisputable that there can be no transmission unless a person is first infected, the chances of which are reduced by vaccination. Ex. D, Salmon Report, at 11-12. Thus, Dr. McCullough's opinion that viral loads among vaccinated persons are similar to those among unvaccinated persons has nothing to do with whether exempting an employee from a vaccination mandate (and thereby increasing the risk of that person contracting COVID-19) causes an undue hardship by imperiling the health and safety of patients and staff. The Court therefore should exclude this opinion.

V. CONCLUSION

For the reasons set forth above, Defendant, VIA Affiliates d/b/a Doylestown Health Physicians, respectfully requests that the Court exclude and strike from the record the Expert Report of Dr. Peter A. McCullough, MD, MPH, and preclude Dr. McCullough from offering any expert testimony in this matter.

Respectfully submitted,

/s/ Christopher D. Durham

Christopher D. Durham, Esquire
Adam D. Brown, Esquire
Elisabeth G. Bassani, Esquire
Duane Morris LLP
30 South 17th Street
Philadelphia, PA 19103
(215) 979-1800

Date: May 12, 2025

Attorneys for Defendant, VIA Affiliates d/b/a Doylestown Health Physicians

Exhibit A

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

\- - -

JOSEPH S. AUTERI, M.D.	:	Civil Action
Plaintiff	:	No. 2:22-cv-03384
	:	
V.	:	
	:	
VIA AFFILIATES, D/B/A	:	
DOYLESTOWN HEALTH	:	
PHYSICIANS	:	
Defendant	:	

\- - -

January 31, 2025

\- - -

CONFIDENTIAL

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Video deposition of JOSEPH S. AUTERI, MD, taken pursuant to notice, was conducted at the law offices of DUANE MORRIS LLP, 30 South 17th Street, 12th Floor, Philadelphia, Pennsylvania 19103, commencing at 9:55 a.m., on the above date, before Susan B. Berkowitz, a Registered Professional Reporter and Notary Public in the Commonwealth of Pennsylvania.

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A. No. I was advocating in favor of all employees, no matter, janitor to the CEO. If they want a religious exemption, we should grant it. That's what I was advocating for. "I" and "we" has nothing to do with that.

And by the way, they're all "we."

Q. Could you please turn to the second page of Auteri-20, the Bates label 152.

A. The second page of the same letter?

Q. Yeah.

A. Yes.

Q. Auteri-20. Yes.

A. I'm there. Yes.

Q. Do you see where it begins: I have recently been?

A. The second paragraph?

Q. Second paragraph.

A. Yes.

Q. Could you please read the second through the -- through the fourth

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paragraphs.

A. I have recently been through a similar season of prayer and fasting regarding the vaccine mandate. I'm being led by the Holy Spirit to respectfully decline the COVID vaccine. I believe my body belongs to God and is the temple of his Holy Spirit. As it says in 1 Corinthians 6:19 and 20, quote, do you not know that your body is a temple of the Holy Spirit, who is in you, whom you have from God, and that you are not your own? For you have been bought with a price: Therefore, glorify God in your body. End quote.

I believe that for me to ingest this vaccine is a violation of the Holy Spirit's leading, and, therefore, would be sin.

When considering whether to obey all the various laws of mankind, or not to obey them, relies on whether or not those same laws would cause me to disobey my understanding of God's Words, if I were to follow Man's rules. In a situation where,

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in order to obey Man's rules or laws I would have to disobey God's word, I must obey God and His Word. Therefore, I am unable to submit to this vaccine mandate imposed by the hospital -- by Doylestown Hospital.

To deny the clear leading of the Spirit would be sinful on my part, and I have no desire to do this. I have a peace about this decision, which I believe the Holy Spirit gives when one is being led by the Spirit.

Title VII of the Civil Rights Act --

Q. That was all that I was -- I just asked you to read the second through the fourth.

A. Oh, you don't want the bottom one?

Q. I don't need the bottom one.

The -- I think you've testified earlier that you spent, you know, time for working on this.

Does what you just read, the second through the fourth paragraphs, fully

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capture the basis of your request for religious exemption from the COVID-19 vaccine mandate, as submitted on October 11, 2021?

MS. RUSSELL: Objection.

You can answer.

THE WITNESS: I don't know if "fully" is the right word there, but, yes, it captivates what my thoughts were. Yes.

BY MR. DURHAM:

Q. Other than what is included in this letter, A-20, did you communicate any basis for your religious exemption request in writing to Doylestown Hospital?

MS. RUSSELL: Objection.

You can answer.

THE WITNESS: Yes. This is the letter that was written October 6th; hand-delivered October 11th.

We then submitted a second request when this request was summarily denied; the second request which then included our suggestion

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on accommodation.
BY MR. DURHAM:
Q. So then does this request -- not the second request -- and we'll get to that second request -- fully capture the basis for your request from religious exemption under the COVID-19 vaccine mandate?
MS. RUSSELL: Objection.
You can answer.
THE WITNESS: I think this doesn't say that part of my rejecting it was that it was an mRNA. That's where the, quote, vaccine, comes in. It was an mRNA vaccine, which is not an attenuated virus, or small amounts of virus.
The vaccine label -- the vaccine definition changed, and it became outside of where I was comfortable when they're trying to change my DNA.
BY MR. DURHAM:
Q. "They" being?
A. The people who created the

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vaccine. I don't believe that's consistent with my religious belief that we shouldn't mess with people's DNA.
Q. So then this letter, and what you've just explained about the mRNA, does that fully capture the basis for your religious exemption request?
MS. RUSSELL: Objection.
You can answer.
THE WITNESS: And add the then subsequent second one.
MR. DURHAM: The content of the second one.
THE WITNESS: Then, yes.
BY MR. DURHAM:
Q. Did you ever communicate anything about that mRNA piece, that you just testified to, to Doylestown Health?
MS. RUSSELL: Objection.
You can answer.
THE WITNESS: Verbally, perhaps. I doubt in writing.
BY MR. DURHAM:
Q. You understood that you were

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required to submit the exemption request in writing, right?
MS. RUSSELL: Objection.
You can answer.
THE WITNESS: I did submit the exemption request in writing. I'm not sure what you're getting at.
Twice.
BY MR. DURHAM:
Q. Oh. So let's -- let's go to -- you say -- in the last paragraph, you say: I look forward to accepting your reasonable accommodation so that we can together continue this wonderful work we are doing at Doylestown Health.
Did you propose any accommodation in this letter?
MS. RUSSELL: Objection.
You can answer.
THE WITNESS: I think you can see from the letter I did not. I thought the way it worked was, I request it. They say we can do it, if you do this, that or the other.

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I thought that's how this works. That's why there's an HR Department that knows the laws that say you have to offer reasonable accommodation.
I didn't know I was supposed to offer a reasonable accommodation.
A week or two later, my attorney gets involved and says, let's offer it anyway.
So, no, I did not, in this letter, as you can see.
BY MR. DURHAM:
Q. Did you discuss this letter with anyone at Doylestown Health?
MS. RUSSELL: Objection.
You can answer.
THE WITNESS: You're talking about verbally?
MR. DURHAM: Yes, verbally.
THE WITNESS: When I handed it to Barb, I may have discussed it. I don't recall.
I also handed her, at the exact

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at Doylestown -- from Doylestown Hospital Management notify you about the testing program that is reflected in Auteri-34, Pages 245 and 246?

MR. DURHAM: Objection. Lacks foundation.

THE WITNESS: No one from anywhere in Doylestown Management notified me of the program.

BY MS. RUSSELL:

Q. In January of 2022, did anyone from Doylestown Hospital Management offer you reinstatement if you were willing to follow the testing program that is reflected in Auteri-34?

MR. DURHAM: Objection. Lacks foundation.

THE WITNESS: No, they did not.

BY MS. RUSSELL:

Q. In January 2022, by that time, had you had signed any other employment agreement which would have precluded you from accepting an offer of reinstatement at Doylestown, subject to this testing program,

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had it been offered to you?

MR. DURHAM: Objection to the form, and lack of foundation.

THE WITNESS: No, I hadn't signed anything.

BY MS. RUSSELL:

Q. Dr. Auteri, you were asked quite a bit of -- of questions, quite a number of questions earlier in the day about data, about the effectiveness of the COVID-19 vaccines.

Do you recall Mr. Durham questioning you at length about data, and discussions that you had about data?

A. I recall, yes.

Q. All right.

For the purpose of my question, I want you to assume that there was no conflict in any data, and that it was agreed by everyone that the mRNA vaccines were safe; whatever that means. Just presume that for the sake of this question.

Do you understand that?

A. That the vaccines were safe?

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Q. Correct. The mRNA vaccines.

A. Presume we had proof that they were safe.

Q. I want you to just assume that. Okay?

A. Okay.

Q. Presuming that the mRNA vaccines were determined to be safe, and there wasn't any disputed data about that, would you have taken the mRNA vaccines and complied with the mandate?

MR. DURHAM: Object to the form.

THE WITNESS: No, I would not.

BY MS. RUSSELL:

Q. Why?

A. Because the mRNA vaccines, by definition, alter DNA and RNA in the recipient, and that goes against my deeply-held religious conviction 1 Corinthians 6:19, for, do you not know your body is a temple of the Holy Spirit given to you by God, glorified God in your body.

No, I would not have taken the mRNA vaccine, which is why I was waiting

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till the last moment to see if the non-mRNA vaccine -- I believe it was called Novavax, although I may be off on that -- was being developed in Maryland, and it was close, and can I wait? Will that happen in time?

But, no, I would not have taken an mRNA vaccine.

MS. RUSSELL: That's all I have. Thank you.

MR. DURHAM: Just a couple of more questions for me.

- - -

EXAMINATION

- - -

BY MR. DURHAM:

Q. Dr. Auteri, A-34, or Auteri-34, I'll keep my focus on the first page, P-245.

Who sent that first e-mail; the bottom of the page?

MS. RUSSELL: Objection. There's been a privilege that's been -- or an objection that has been asserted. There's been a privilege log that's been produced. And we

Exhibit B

Kaplin Stewart
Attorneys at Law

Kimberly L. Russell, Esquire
Direct Dial: (610) 941-2541
Direct Fax: (610) 684-2026
Email: krussell@kaplaw.com
www.kaplaw.com

October 22, 2021

EMAIL AND REGULAR MAIL

Barbara Hebel, VP, Human Resources
Doylestown Health
595 West State Street
Doylestown, PA 18901

RE: Joseph S. Auteri, M.D.

Dear Ms. Hebel:

Kaplin Stewart Meloff Reiter & Stein, P.C. represents Joseph S. Auteri, M.D. This is in response to your letter dated October 13, 2021 which improperly denied Dr. Auteri's requests for an exemption from Doylestown Health System's and VIA Affiliates' (collectively, **"DH"**) COVID-19 vaccination requirement and memorialized DH's refusal to engage in the interactive process to establish a reasonable accommodation for Dr. Auteri. The purpose of this letter is to provide DH with the opportunity to reconsider its legal violations of Dr. Auteri's rights, provide Dr. Auteri with reasonable accommodations, cease DH's breach of Dr. Auteri's contractual rights and slander of Dr. Auteri, and remedy the retaliation Dr. Auteri suffered following Dr. Auteri's report of harassment and a hostile work environment.

Timing of Dr. Auteri's Exemption Requests

Your October 13, 2021 letter denies Dr. Auteri's medical and religious exemption requests in part because those requests allegedly were received after DH's alleged "deadline" of September 10, 2021. That establishment of an arbitrary deadline and apparent adherence to such a deadline is a violation of state and federal law. Title VII of the Civil Rights Act of 1964 (**"Title VII"**), the Americans with Disabilities Act (**"ADA"**), and the Pennsylvania Human Relations Act (**"PHRA"**) do not permit employers to establish "deadlines" beyond which an employee is not permitted to seek an exemption from a workplace standard and resulting reasonable accommodation request. To the extent that DH denied Dr. Auteri's exemption requests in whole or in part due to Dr. Auteri's alleged failure to meet DH's "deadline" for such requests, DH must reconsider those requests immediately in order to avoid a claim for a violation of Dr. Auteri's civil rights.

[redacted]

Dr. Auteri's Request for Medical Exemption and Reasonable Accommodation

Dr. Auteri submitted a valid request for medical exemption to DH's COVID-19 vaccine mandate on October 6, 2021 and enclosed with this letter is another request for medical exemption. The enclosed exemption request is a certification by Dr. Auteri's treating physician that Dr. Auteri should not receive the COVID-19 vaccine. Dr. Auteri's request meets the requirements to obtain a reasonable accommodation under the ADA and PHRA. DH's refusal of Dr. Auteri's prior request for medical exemption based upon CDC guidance is improper under the ADA and PHRA.[1] CDC guidance is just that – guidance – and not law which supersedes the ADA and PHRA. CDC guidance does NOT permit the violation of an employee's civil rights. Even the CDC guidance as cited in your October 13, 2021 letter merely "recommends" that health care providers "offer" vaccination regardless of prior infection. CDC guidance is not a lawful basis to deny a valid request for medical exemption. Dr. Auteri expects that DH will grant his medical exemption request and grant the reasonable accommodation requested below, which accommodation is consistent with DH's past and current practices to mitigate the risk of COVID-19 exposure and transmission in DH facilities.

[redacted]

Dr. Auteri's Request for Religious Exemption and Reasonable Accommodation

Dr. Auteri submitted a valid request for a religious exemption to DH's COVID-19 vaccine mandate on October 6, 2021. In that request, Dr. Auteri articulated a sincerely held religious belief which exceeds the requirements to grant such an exemption. Dr. Auteri articulated that as a person of faith and follower of Jesus Christ, his sincerely held religious beliefs do not permit him to take the COVID-19 vaccine. DH is not permitted as a matter of law under Title VII or the PHRA to deny such an exemption request, and certainly cannot deny that request because of the request's "untimeliness" as discussed above. Your statement that the grant of a legally protected exemption from a workplace standard on the basis of a sincerely held religious belief would be "special treatment" is a violation of Dr. Auteri's civil rights which DH must cure immediately to avoid legal action. Dr. Auteri expects that DH will grant his religious exemption request and grant the reasonable accommodation requested below, which accommodation is consistent with DH's past and current practices to mitigate the risk of COVID-19 exposure and transmission in DH facilities.

[redacted]

Dr. Auteri's Reasonable Accommodation Request

In your October 13, 2021 letter denying Dr. Auteri's exemption requests, after denying those valid requests in violation of Dr. Auteri's civil rights, you summarily state that no accommodation would be available which would enable Dr. Auteri to perform his work and not impose an "undue hardship" on DH "because the safety of the vulnerable and high-risk patient population" which Dr. Auteri treats would be "jeopardized" by Dr. Auteri's vaccine exemption,

[1] DH also has acknowledged the potential for the COVID-19 "vaccine" to cause harmful side effects, as DH offered to compensate Dr. Auteri if the vaccine resulted in a side effect which would preclude Dr. Auteri from performing surgery. Dr. Auteri's proposed reasonable accommodation described in this letter addresses patient safety, Dr. Auteri's medical condition, and potential adverse side effects from the vaccine.

as determined by "DH Infection Control." Leaving aside the qualifications of those involved in "DH Infection Control" as it relates to COVID-19 matters, your statement that no accommodation is available is false and a violation of Dr. Auteri's civil rights.

When an employee is entitled to an exemption from a workplace standard on the basis of a medical or religious reason, the employer must engage in an interactive process with the employee to determine, in joint consultation, whether a reasonable accommodation is available. Employers who claim that they cannot grant a reasonable accommodation due to an "undue hardship" have an exceedingly high burden to meet. Your letter fails entirely to articulate that hardship and violates Dr. Auteri's civil rights. Contrary to your statement, a reasonable accommodation is available and is readily achievable by DH as a healthcare provider and facility.

Dr. Auteri requests that his exemption requests be granted and that as a reasonable accommodation, Dr. Auteri submit to (1) a daily healthcare screening in which Dr. Auteri's temperature is taken and Dr. Auteri certifies that he has not been exposed to or experiencing any symptoms of COVID-19, and (2) weekly COVID-19 testing. DH certainly can conduct such basic screenings and the additional time and/or expense required to do so does not meet the high burden to demonstrate an "undue hardship." DH has conducted health screenings and COVID-19 testing throughout the pandemic and now cannot claim an undue hardship in doing so. Nor can DH legally claim that Dr. Auteri remaining unvaccinated but subject to testing jeopardizes patient safety because DH's Vice President and Chief Medical Officer, Scott Levy, M.D. acknowledged in an August 15, 2021 email to the Bucks County Health Commissioner (copy enclosed) "the ability of the vaccinated to transmit the virus [i.e. COVID-19]." DH's denial of Dr. Auteri's privileges of employment due to his need for an exemption to the vaccine mandate and reasonable accommodation, where DH admits through one of its top executives that vaccinated individuals can transmit COVID-19, is a violation of Dr. Auteri's civil rights. By agreeing to daily health screenings and weekly testing for COVID-19, Dr. Auteri poses less of a COVID-19 transmission risk than vaccinated personnel who are capable of transmitting the virus but not subjected to testing. Dr. Levy also previously equated patients who have been vaccinated with those who have already been infected with COVID-19 and exempted those patients from pre-procedure COVID-19 testing. See Dr. Levy's January 8, 2021 email (copy enclosed) stating in pertinent part "[a]nalogous to patient (sic) who have already had infection with COVID; those individuals who have been fully vaccinated for Covid do NOT need to have preprocedure testing done." There can be no lawful, nondiscriminatory, and/or nonretaliatory basis to deny Dr. Auteri's requested reasonable accommodation.

Breach of Dr. Auteri's Contractual Rights

The claims in your October 13, 2021 letter that Dr. Auteri has breached his Employment Agreement are based upon the entirely false premise that Dr. Auteri engaged in conduct which jeopardizes patient safety and justifies the revocation or suspension of Dr. Auteri's privileges. As demonstrated above, Dr. Auteri has engaged in no conduct which jeopardizes patient safety and Dr. Auteri's proposed reasonable accommodation actually makes him less of a "hazard" to

patient safety than untested, vaccinated individuals who, by DH's admission, also are capable of transmitting the COVID-19 virus. Contrary to the claims in your October 13, 2021 letter, DH is in breach of Dr. Auteri's Employment Agreement because DH suspended Dr. Auteri's privileges without cause and then used that improper suspension to give notice of Dr. Auteri's impending termination. Dr. Auteri hereby demands that DH immediately reinstate Dr. Auteri's privileges, pay to Dr. Auteri all lost pay and benefits, and provide the reasonable accommodation requested above. If DH fails to do so and terminates Dr. Auteri in violation of the Employment Agreement, Dr. Auteri will take legal action against DH for breach of contract and seek all available remedies against DH. DH cannot breach Dr. Auteri's Employment Agreement and then seek to benefit from DH's breach by terminating Dr. Auteri in violation of that Agreement. DH must cure its breach immediately.

Dr. Auteri has Communicated Truthfully with Third Parties about DH's Improper Conduct and DH's Threat to Terminate Dr. Auteri's Employment

In your October 13, 2021 letter, you falsely accused Dr. Auteri of telling third parties that he "has been terminated" and "interfering with [DH's] business relationship with those third parties." I do not know the basis of your false statements, but your statements are without basis in fact and seem only to evidence DH's continued retaliation against Dr. Auteri (discussed in further detail below). Enclosed is a copy of Dr. Auteri's October 16, 2021 text message, which he has sent multiple times to multiple individuals, in which Dr. Auteri accurately states that (1) Dr. Auteri requested an exemption from the vaccine mandate, (2) DH then placed Dr. Auteri on an unpaid suspension, and (3) "in 30 days that will turn into a termination." Dr. Auteri's text is an entirely accurate summary and representation of Brenda Foley, M.D.'s October 11, 2021 letter to Dr. Auteri stating in pertinent part that Dr. Auteri is "being placed on a 30 day precautionary suspension from the medical staff" and your October 13, 2021 letter stating that if Dr. Auteri does not "cure his breach" by submitting proof of vaccination, DH "will terminate [Dr. Auteri's] employment for cause." Do not again accuse Dr. Auteri of "interfering with DH's business relationships" without first obtaining evidence of that interference. Dr. Auteri is permitted to communicate with employees and third parties about the terms and conditions of his employment and such communications are protected as a matter of law under the National Labor Relations Act.

DH's Slander of Dr. Auteri

It has come to Dr. Auteri's attention that DH has instructed staff in Dr. Auteri's office to advise patients seeking care that Dr. Auteri is on a "personal leave of absence." That statement is absolutely false and misleads patients. Stating that Dr. Auteri is on a personal leave of absence falsely implies that Dr. Auteri requested and/or is taking a leave of absence due to some problem with Dr. Auteri which renders Dr. Auteri unable to care for Dr. Auteri's patients. Nothing could be further from the truth, and DH's directive to the staff in Dr. Auteri's office is directing the slander of Dr. Auteri which will lead patients to question Dr. Auteri's fitness to practice medicine. Such a result damages Dr. Auteri's reputation by DH's knowingly false statement and constitutes slander. DH has suspended Dr. Auteri due to DH's improper denial of Dr.

Auteri's requests for an exemption from the COVID-19 vaccine mandate and reasonable accommodation. If DH insists upon communicating about Dr. Auteri's absence from work, DH should state the truth or communicate nothing at all. If DH continues damaging Dr. Auteri in such a manner, Dr. Auteri will take appropriate legal action. DH cannot evade the consequences of its unlawful violations of Dr. Auteri's civil rights by defaming Dr. Auteri's reputation.

DH's Retaliation Against Dr. Auteri Following Dr. Auteri's Report of Harassment and a Hostile Work Environment

On September 10, 2021, Dr. Auteri reported that he was being subjected to harassment and a hostile work environment by Dr. Levy, Dr. Auteri's direct supervisor. Dr. Auteri copied you on an email in which he specifically stated that Dr. Levy was repeatedly engaging with Dr. Auteri in a "heated," "angry" way and with a raised voice. Dr. Levy repeatedly has yelled at and demeaned Dr. Auteri in front of other DH staff. Dr. Auteri reported that Dr. Levy was unable to have a conversation with Dr. Auteri without Dr. Levy becoming "agitated." As a Human Resources professional, you certainly must be aware that your receipt of such a communication triggers your obligation to investigate further Dr. Auteri's allegations. Dr. Auteri is entitled to know exactly what was done to investigate his complaint and the result of that investigation. As of this writing, you have not provided that investigation information to Dr. Auteri. Please provide me with that investigation information immediately, including evidence of the action you took to rectify Dr. Levy's improper conduct.

Following that report of harassment and a hostile work environment, DH retaliated against Dr. Auteri by summarily denying Dr. Auteri's exemption requests, failing to grant Dr. Auteri a reasonable accommodation and without engaging in the interactive process as required by law, and suspending Dr. Auteri in breach of Dr. Auteri's Employment Agreement and violation of Dr. Auteri's civil rights. On October 16, 2021, Dr. Auteri again reported "abuse" and "harassment" at the hands of Dr. Levy. On October 10, 2021, Dr. Levy threatened Dr. Auteri by telling Dr. Auteri that Dr. Auteri would be terminated immediately if Dr. Auteri did not forfeit Dr. Auteri's civil rights and comply with the "vaccine mandate." Dr. Levy harassed Dr. Auteri and said that Dr. Auteri's "legacy" would be that of a "loser" if Dr. Auteri did not forfeit Dr. Auteri's civil rights by succumbing to the "mandate." Dr. Levy threatened Dr. Auteri's business reputation and welfare by stating that Dr. Auteri would never get a job as a cardiac surgeon in the United States again if Dr. Auteri did not forfeit Dr. Auteri's civil rights and succumb to the mandate. Dr. Levy violated HIPAA in the course of Dr. Levy's threats by naming three other unvaccinated physicians on the DH staff, defamed those physicians by stating that Dr. Auteri was "not in good company" by failing to comply and forfeit Dr. Auteri's civil rights, all of which was presented as a threat to Dr. Auteri. The day after Dr. Levy's threats and Dr. Auteri's refusal to forfeit his civil rights, and immediately after asserting those rights by requesting exemptions and accommodations, DH retaliated against Dr. Auteri by summarily denying those exemptions and requests for accommodations without appropriate legal justification to do so.

As of this writing, you have had six days to investigate Dr. Auteri's October 16, 2021 report of harassment and retaliation. Dr. Auteri is entitled to know exactly what was done to investigate

his complaint and the result of that investigation. As of this writing, you have not provided that investigation information to Dr. Auteri. Please provide me with that investigation information immediately, including evidence of the action you took to rectify Dr. Levy's improper conduct. Dr. Levy apparently has no intention of ceasing his improper conduct, and DH apparently cannot control Dr. Levy's improper conduct. DH apparently took no action to rectify Dr. Levy's conduct following notice to you on September 10, 2021, and Dr. Levy believed that he could continue his improper conduct and retaliate against Dr. Auteri. Dr. Auteri hereby demands that DH commence an immediate investigation of Dr. Levy's conduct and that Dr. Levy be removed from DH premises pending the outcome of that investigation so that Dr. Auteri and all DH staff are not subjected to Dr. Levy's improper and uncontrolled conduct.

Conclusion

Dr. Auteri expects that his exemption requests will be granted and reasonable accommodations adopted as set forth above. Dr. Auteri expects that he will be reinstated immediately and all lost pay and benefits restored. Dr. Auteri will not forfeit his civil rights and will not tolerate DH's continued violation of those rights and refusal to protect Dr. Auteri's rights as stated herein. Make no mistake - Dr. Auteri is not resigning as stated in Dr. Foley's October 11, 2021 letter and on November 11, 2021, if DH pursues its wrongful path as stated in your October 13, 2021 letter and terminates Dr. Auteri's employment, DH will do so in violation of Dr. Auteri's civil rights and Employment Agreement.

If DH has denied other employee's exemption requests as it did Dr. Auteri's and failed to provide reasonable accommodations as required by law, DH had best reconsider and rectify its decisions or DH may be subject to class litigation for DH's civil rights violations, which litigation would seemingly be meritorious on its face. It is unfathomable that DH would flagrantly violate its employees' civil rights and terminate staff or otherwise retaliate against highly skilled staff by effectively demoting those employees to lower paying positions and at the same time jeopardizing patient safety by reducing the availability of such staff. DH is demonstrating a complete disregard of its employees' civil rights and its patients' rights to prompt and effective treatment. DH knows that its position is not based in fact and universal employee vaccination will not stop the spread of COVID-19 (per Dr. Levy's admissions). DH must rectify immediately its conduct or face the severe legal consequences.

Sincerely,

KAPLIN STEWART MELOFF REITER & STEIN, P.C.

By: Kimberly L. Russell, Esquire

KLR:dg

Enclosures

Woodlands Healing Research Center
Family, Environmental & Preventive Medicine

10/21/2021.

Re: Joseph Auteri
3007 Holicong Road
Doylestown, PA 18902-

To Whom It May Concern,

I am the treating physician of Joseph Auteri, M.D.
Based upon his current medical status and condition, I do not recommend COVID-19 vaccination.

Sincerely,

Provider:
Kracht DO, William 10/21/2021 1:09 PM

Document generated by: William Kracht 10/21/2021

Woodlands Healing Research Center
Integrative Family Medicine
5724 Clymer Rd., Quakertown, PA 18951
www.woodmed.com / foffice@woodmed.com
Phone: 215-536-1890 / Fax: 215-529-9034

Exhibit C

Exhibit Filed Under Seal

Exhibit D

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

Joseph S. Auteri, M.D. Plaintiff; v. VIA *Affiliates, d/b/a Doylestown Health Physicians*, Inc., Defendant.	Civil No. 22-CV-03384

EXPERT REPORT OF DR. PETER A. MCCULLOUGH, MD, MPH

I. INTRODUCTION, QUALIFICATIONS, AND PRIOR TESTIMONY.

A. Introduction.

I have contributed extensively to public policy making on issues surrounding the COVID-19 crisis through a series of OPED's for *The Hill* in 2020.[1] I have had numerous public political appearances addressing pandemic issues listed on CSPAN.[2] Since 2021, I have been publishing a weekly contribution on *America Out Loud, The McCullough Report.*[3] Since 2022, I have daily postings with graphical abstracts, interviews, and reports on *Courageous Discourse Substack.*[4]

My expertise on the SARS-CoV-2 infection and COVID-19 syndrome also includes the review of hundreds of manuscripts and the care of many patients with acute COVID-19 illness, post-acute sequelae after SARS-CoV-2 infection, long-COVID, and COVID-19 vaccine injury including cardiovascular, thrombotic, neurologic, autoimmune and neoplastic syndromes that have arisen after mRNA, adenoviral DNA, and antigen-based vaccines. I have formed my opinions in close communications with many clinicians around the world based in part on our collective clinical experience throughout the pandemic.

I am currently in independent practice where I see and examine patients on a daily basis with acute COVID-19, long-COVID syndrome, and COVID-19 vaccine injuries and disabilities.[5] I am President of the McCullough Foundation, a not-for-profit organization dedicated to investigative scholarship, educational media, justice, and public policy.[6] Finally, I am the part-time Chief Scientific Officer of the Wellness Company.[7]

A true and correct copy of my Curriculum Vitae is attached hereto as EXHIBIT A and incorporated herein.

B. Qualifications.

Pursuant to Fed. R. Civ. P. 26(a)(2)(B)(iv), I hereby provide my qualifications as an expert in the matters presented herein.[8] After receiving a bachelor's degree from Baylor University, I completed my medical degree as an Alpha Omega Alpha graduate from the University of Texas Southwestern Medical School in Dallas. I went on to complete my internal medicine residency at the University of Washington in Seattle, a cardiology fellowship including service as Chief Fellow at William Beaumont Hospital, and a master's degree in public health in the field of epidemiology at the University of Michigan. I am board certified by the National Board of American Physicians and Surgeons in internal medicine and cardiovascular diseases.[9] I am an active scholar in medicine with roles as an author, editor-in-chief, editorialist, and reviewer of dozens of major medical journals and textbooks. I have led clinical, education, research, and program operations at major academic centers (Henry Ford Hospital, Oakland University William Beaumont School of Medicine) as well as academically oriented community health systems.[10] I spearheaded the clinical development of in vitro natriuretic peptide and neutrophil gelatinase associated lipocalin assays in diagnosis, prognosis, and management of heart and kidney disease now used worldwide. I also led the first clinical study demonstrating the relationship between severity of acute kidney injury and

mortality after myocardial infarction.[11] I have contributed to the understanding of the epidemiology of chronic heart and kidney disease through many manuscripts in the Kidney Early Evaluation Program Annual Data Report published in the American Journal of Kidney Disease, and participated in clinical trial design and execution in cardiorenal applications of acute kidney injury, hypertension, acute coronary syndromes, heart failure, and chronic cardiorenal syndromes.[12] I participated in event adjudication (involving attribution of cause of death) in trials of acute coronary syndromes, chronic kidney disease, heart failure, and data safety and monitoring of antidiabetic agents, renal therapeutics, hematology products, and gastrointestinal treatments. I have served as the chairman or as a member of over 20 randomized trials of drugs, devices, and clinical strategies. Sponsors of these trials have included pharmaceutical manufacturers, biotechnology companies, and the National Institutes of Health.

I frequently lecture and advise on internal medicine, nephrology, and cardiology to leading institutions worldwide. I am recognized by my peers for my work on the role of chronic kidney disease as a cardiovascular risk state. I have over 1,000 related scientific publications, including the "Interface between Renal Disease and Cardiovascular Illness" in *Braunwald's Heart Disease Textbook*.[13] My works have appeared in the *New England Journal of Medicine*,[14] *Journal of the American Medical Association*,[15] and other top-tier journals worldwide. I have testified before the U.S. Food and Drug Administration Cardiorenal Advisory Panel and its U.S. Congressional Oversight Committee in 2007. I have been a Fellow of the American Heart Association, the American College of Physicians, the American College of Chest Physicians, the National Lipid Association, the Cardiorenal Society of America, and the National Kidney Foundation; and I am also a Diplomate of the American Board of Clinical Lipidology. In 2013, I was honored with the International Vicenza Award for Critical Care Nephrology for my contribution and dedication to

the emerging problem of cardiorenal syndromes.[16] I am a founding member and former President of Cardiorenal Society of America, an organization that brought together cardiologists and nephrologists to engage in research, improved quality of care, and community outreach to patients with both heart and kidney disease.[17] I am the current Editor-in-Chief of *International Journal of Cardiovascular Research & Innovation*[18] and the Clinical Section Editor of *Science, Public Health Policy and the Law*.[19]

Since the outset of the pandemic, I have been a leader in the medical response to the COVID-19 disaster and have published "Pathophysiological Basis and Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection," the first synthesis of sequenced multidrug treatment of ambulatory patients infected with SARS-CoV-2 in the *American Journal of Medicine*[20] and updated in *Reviews in Cardiovascular Medicine*.[21] Subsequently I published the first detoxification approach titled "Clinical Rationale for SARS-CoV-2 Base Spike Protein Detoxification in Post COVID-19 and Vaccine Injury Syndromes" in the *Journal of American Physicians and Surgeons*[22] and updated in the *Cureus Journal of Biomedical Science in 2024*.[23] I have over 100 peer-reviewed publications, abstracts, letters, and preprints concerning COVID-19 infection and vaccine safety cited in the National Library of Medicine, Google Scholar, and other indexes.

C. Prior Testimony.

My government sworn testimony on the COVID-19 pandemic is summarized below.

<u>Testimony for Government</u>

1. US Senate Homeland Security and Governmental Affairs, lead witness, Early Outpatient Treatment of COVID-19: An Essential Part of a COVID-19 Solution, Majority Chairman, Sen Ron Johnson (R-WI), Minority Chair Gary Peters, (D-MI)
2. US Senate Panel, co-moderator with Sen Ron Johnson (R-WI), COVID-19: A Second Opinion January 24, 2022

3. US Senate Panel, co-moderator with Sen Ron Johnson (R-WI), Sen Roger Marshall (R-KS), COVID-19 Vaccines: What they Are, How They Work, and Possible Causes of Injuries, December 7, 2022
4. Texas Senate Committee on Health and Human Services on March 10, 2021, June 28, 2022, COVID-19 Pandemic Response, Treatment, Vaccines
5. Colorado General Assembly, Early Therapeutics for COVID-19, March 31, 2021
6. New Hampshire Senate, legislation concerning COVID-19 vaccines, April 14, 2021.
7. Pennsylvania State Senate, Medical Freedom Panel under the Senate Veterans Affairs and Emergency Preparedness Committee, March 1, 2022, June 9, 2023.
8. South Carolina Health and Human Services Committee, Medical Affairs Select Subcommittee, September 22, 2021
9. Novel Coronavirus Southwestern Intergovernmental Committee, Arizona House of Representatives and Senate, May 25, 2023, October 20, 2023, March 15, 2024
10. European Parliament Expert Hearing on Health and Democracy under WHO's Proposed New Rules, Benefits and Risks to Civil Society, EU Parliament Strasbourg, MEP Christine Anderson, Chair, September 13, 2023
11. Brazil's Chamber of Deputies, National Congress of Brazil. Recommendation Against Childhood COVID-19 Vaccination. Brazil, November 21, 2023.
12. United States House of Representatives, COVID-19 Vaccine Injury Panel, Chair Representative Majorie Taylor Greene R-GA, January 12, 2024

Pursuant to Fed. R. Civ. P. 26(a)(2)(B)(v), in the last several years, and in addition to the numerous times I have provided expert testimony to state legislatures and the committees of the United States Congress, I have provided expert testimony multiple districts and federal courts as indicated in appendices.

D. Compensation.

Pursuant to Fed. R. Civ. P. 26(a)(2)(B)(vi), I am being compensated $750 per hour for my time as an expert in this case.

E. Materials Reviewed.

In support of the opinions in this report, in addition to the many medical and scientific materials cited above, I have reviewed the following materials specific to Dr. Auteri's case:

1. Second Amended Complaint and all Exhibits thereto, including the

Exemption Requests, Second Exemption Request, and resulting denials.

2. Doylestown Health's COVID-19 Vaccine Mandate.

3. Doylestown Health's COVID-19 Vaccines "FAQ's."

4. Email dated August 15, 2021 from Doylestown Health Chief Medical Officer Scott Levy, M.D. admitting that vaccinated persons can transmit "live" COVID-19 virus. (Document P265).

5. Emails from Dr. Levy dated January 7, 2022 (Documents P-247-248) and January 26, 2022 (Documents P302-303) permitting COVID-19 infected employees to return to work WITHOUT TESTING provided that symptoms were improved.

6. Transcripts of depositions of James Brexler, Scott Levy, and Barbara Hebel.

II. EXPERT OPINIONS AND THE BASES FOR SUCH OPINIONS.

A. Introductory Opinions.

1. I believe within a reasonable degree of medical certainty that the COVID-19 vaccine(s) offered at the time of Dr. Auteri's termination in November 2021 are gene therapy products which have the ability to alter an individual's human genome, and Dr. Auteri's expressed religious concern about those vaccines was supported by the data available at that time.

2. I believe within a reasonable degree of medical certainty that Dr. Auteri presented no increased safety risk to Defendant Doylestown Health's[1] patients or staff and that Dr. Auteri's proposed reasonable accommodation of weekly testing and daily health screenings provided better safety protection to patients and staff than Doylestown Health's reliance upon the COVID-19 vaccines, which Doylestown Health knew did not stop COVID-19 transmission. Dr. Auteri's proposed accommodation presented no undue burden but offered patients "real time" assurances that Dr. Auteri was not infected with the COVID-19 virus. By contrast, Doylestown Health knew

[1] Defendant VIA Affiliates, d/b/a Doylestown Health Physicians, Inc. is referred to in this report as "Doylestown Health."

vaccinated staff members could transmit the COVID-19 virus but was not testing vaccinated staff members unless those members showed significant symptoms. The Centers for Disease Control (**"CDC"**) reported that the COVID-19 vaccines reduced the severity of illness in infected persons, and Doylestown Health's vaccinated staff members likely were spreading the COVID-19 virus to patients and staff because those staff members were infectious and not being tested absent significant symptoms. Doylestown Health's reliance on the COVID-19 vaccines to protect patient safety was knowingly deficient and not justified by the data available from the Summer of 2021 through the time of Dr. Auteri's termination in November 2021.

The basis for each of the above opinions is discussed in detail below.

B. Foundational Bases for Expert Opinions.

1. Opinion as to COVID-19 Vaccines as Gene Therapy Products.

The Pfizer, Moderna, and Johnson & Johnson (Janssen) vaccines are considered "genetic vaccines," or vaccines produced from gene therapy molecular platforms which, according to US FDA regulatory guidance, are classified as gene delivery therapies and should be under a 15-year regulatory cycle with annual visits for safety evaluation by the research sponsors. Food and Drug Administration, *Long Term Follow-up After Administration of Human Gene Therapy Products. Guidance for Industry*.[24] The FDA has "advised sponsors to observe subjects for delayed adverse eventsfor as long as 15 years following exposure to the investigational gene therapy product, specifying that the long-term follow-up observation should include a minimum of five years of annual examinations, followed by ten years of annual queries of study subjects, either in person or by questionnaire." Before Novavax was introduced[2], the available Emergency Use

[2] The Novavax COVID-19 vaccine booster was not available in the timeframe of August through November 2021. Novavax was not granted Emergency Use Authorization until October 2022 and then only as a booster after a primary course of COVID-19 vaccination. Novavax operated in a different manner more akin to "traditional" vaccines but was not available prior to Dr. Auteri's termination.

Authorized vaccines (Pfizer, Moderna, Janssen) were in essence genetic biotechnology products which have been shown to alter the human genome through reverse transcription.[25]

Additionally, the Pfizer and Moderna vaccines have been shown to be contaminated with SV-40 DNA fragments which are known to readily integrate into the human genome without the need for reverse transcription.[26] [27] Thus, the administration of the Moderna, Pfizer, and Janssen vaccines should not be undertaken without the proper consent and arrangements for long-term follow-up which are currently not offered in the US. (*See*, EUA briefing documents for commitments as to follow up: Moderna, Pfizer, Janssen). These novel, genetic vaccines have a dangerous mechanism of action[28] in that they all cause the body to make an uncontrolled quantity of the pathogenic and potentially lethal SARS-CoV-2 spike protein and unwanted frameshifted proteins for at least six months (and probably a longer period, based on the late emergence of vaccine injury reports).[29] [30] [31] This is unlike all other vaccines where there is a set amount of antigen or killed- or live-attenuated virus particles. This means that, for Pfizer, Moderna, and Janssen vaccines, it is not predictable among patients who will produce more or less of the potentially lethal spike protein.[32] Additionally, Pfizer and Moderna mRNA products are expected to have misreading of the mRNA message and produce a dozen or more unwanted frameshifted peptides.[33] The Pfizer, Moderna, and Janssen vaccines, because they are different, are expected to produce different libraries of limited antibodies to the now extinct wild-type spike protein and prior extinct variants with boosters. It is known that the spike protein produced by the vaccines is obsolete (and was obsolete as of April 2022) because the 17th UK Technical Report on SARS-CoV-2 Variants, issued on June 25, 2021, and the CDC Variant Report issued on June 19, 2021, both indicated that the SARS-CoV-2 wild type virus to which all the vaccines

were originally developed was extinct.[34]

The mechanism of action for the Pfizer, Moderna, and Johnson & Johnson (Janssen) "genetic vaccines" has been shown to alter the human genome through reverse transcription and gives pause to many religious objectors who oppose the alteration of their genetic profile as designed by God.

2. Opinion that COVID-19 Vaccine Alone Does Not Promote Patient Safety.

On August 5, 2021, Dr. Rochelle Walensky, head of the CDC announced that the vaccinated can contract and carry the SARS-CoV-2 virus and spread COVID-19 infection to fellow vaccinated individuals.[35] Multiple studies indicated fully vaccinated individuals were carrying large viral loads of SARS-CoV-2 in the nasopharynx and fully capable of spreading the virus to vaccinated or unvaccinated contacts.[36] [37] [38] [39] [40] [41] Salvatore and coworkers stated in their paper published November 19, 2021: "Clinicians and public health practitioners should consider vaccinated persons who become infected with SARS-CoV-2 to be no less infectious than unvaccinated persons." Any school, company, agency or other entity substantially encouraging or mandating COVID-19 vaccination either knew or should have known that mass vaccination would

not stop the spread of SARS-CoV-2 and would not make the classroom, workplace, or public area more safe from COVID-19.

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CDC: COVID vaccines won't stop transmission; Fully vaccinated can still get, spread Delta strain

Mike Sunnucks Aug 5, 2021 0

Dr. Rochelle Walensky, director of the Centers for Disease Control and Prevention, adjusts her face mask during a Senate Health, Education, Labor and Pensions Committee hearing on the federal coronavirus response on Capitol Hill in Washington, in this Thursday, March 18, 2021.

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

The COVID-19 vaccines have never been sufficiently protective against contracting COVID-19. Recurrent SARS-CoV-2 vaccine breakthrough infections were widely reported early in the vaccine campaign. In response to those numerous reports, the CDC announced on May 1, 2021, that community breakthrough cases would no longer be reported to the public and only those vaccine failure cases requiring hospitalization will be reported, presumably on the CDC website.[42] Fully vaccinated patients contract breakthrough infections (except for those vaccinated individuals who were previously immune from prior COVID-19 infection).

By the end of 2021, the CDC reported that the Omicron variant appeared in fully vaccinated persons and was able to spread among those with both natural and vaccine-induced immunity.[43] [44] Analyses from Subramanian, Beattie, and Kampf indicated that mass vaccination

was at best worthless or more concerning, it was making the pandemic worse by fostering more spread of the virus by the vaccinated and promoting new strains of SARS-CoV-2 which were resistant to vaccine immunity.[45] [46] [47] The CDC reported that the COVID-19 vaccines prevented serious illness,[48] but reduced illness and/or symptoms fostered the spread of the virus by the vaccinated who were not showing significant symptoms, were not testing, and were not taking precautions to isolate because those vaccinated persons did not know that they were infected with the virus.

As discussed below, Doylestown Health's reliance on the COVID-19 vaccines without testing unless an infected staff member exhibited significant symptoms likely fostered the spread of the virus and did not create a safe environment.

C. Opinions as Applied to the Specific Facts in this Case

Opinion 1: I believe within a reasonable degree of medical certainty that the COVID-19 vaccine(s) offered at the time of Dr. Auteri's termination in November 2021 are gene therapy (gene transfer technology) products which have the ability to alter an individual's human genome, and Dr. Auteri's expressed religious concern about those vaccines was supported by the data available at that time.

Based upon my review of the above materials, I understand that Dr. Auteri declined COVID-19 vaccination and submitted a request for a religious exemption and accommodation. [3] The basis of Dr. Auteri's religious exemption request was that to Dr. Auteri's understanding, the available Emergency Use Authorized vaccines (Pfizer, Moderna, Janssen) were in essence genetic biotechnology products which have been shown to alter the human genome through reverse transcription.[49] Additionally, the Pfizer and

[3] I understand that Dr. Auteri contracted COVID-19 illness in May, 2021, with confirmatory seropositivity, and also requested a medical exemption. I also understand that a medical exemption request is not at issue in the case at this time so I will not address further the strong, broad immunity from COVID-19 illness and transmission which results from natural COVID-19 infection.

Moderna vaccines have been shown to be contaminated with SV-40 DNA fragments which are known to readily integrate into the human genome without the need for reverse transcription.[50] [51] Dr. Auteri's firmly and sincerely held religious beliefs disallowed injection of genetic product(s) into his body which held the potential to alter Dr. Auteri's genetic profile as designed by God. Dr. Auteri's expressed religious concerns about the potential of the COVID-19 Vaccines to alter Dr. Auteri's genetic profile were well founded based upon the known mechanism of action of those vaccines, which has been shown to alter the human genome through reverse transcription. Those mechanisms of action were known from August through November 2021, the timeframe relevant to Doylestown Health's COVID-19 Vaccine Mandate and Dr. Auteri's termination. Dr. Auteri's sincerely held and expressed religious beliefs were supported by the data known in 2021 and Doylestown Health should not have required any person expressing such a concern to take the COVID-19 Vaccines. Dr. Auteri was unjustly fired when he refused to be injected with COVID-19 "genetic" vaccines.

Opinion 2: I believe within a reasonable degree of medical certainty that Dr. Auteri presented no increased safety risk to Defendant Doylestown Health's patients or staff and that the requested accommodations to undergo weekly testing for COVID-19 infection and to undergo daily health screenings, including daily temperature checks (the "Auteri Accommodations") provided better safety protection to patients and staff than Doylestown Health's reliance upon the COVID-19 vaccines which Doylestown Health knew did not stop COVID-19 transmission.

I believe within a reasonable degree of medical certainty that the Auteri Accommodations presented no undue burden but offered patients "real time" assurances that Dr. Auteri was not infected with the COVID-19 virus, making Dr. Auteri "safer" in caring for vulnerable patients than vaccinated employees and staff who would be expected to carry large viral loads of SARS-CoV-2 in the nasopharynx despite undergoing vaccination at some point which could have been many months in the past from when the COVID-19 vaccine campaign was begun. By contrast, Doylestown Health knew that vaccinated staff members could transmit the COVID-19 virus but was not testing vaccinated staff members

unless those members showed significant symptoms.

The CDC reported that the COVID-19 vaccines reduced symptoms in infected persons, and Doylestown Health's vaccinated staff members likely were spreading the COVID-19 virus to patients and staff because those staff members were infectious and not being tested without self-prompting with significant symptoms. Doylestown Health's reliance on the COVID-19 vaccines to protect patient safety was knowingly deficient, insufficient to address patient safety, and not justified by the data available from the Summer of 2021 through the time of Dr. Auteri's termination in November 2021.

Based upon my review of the above scientific and case-specific materials, I understand that on October 22, 2021, Dr. Auteri offered, as a reasonable accommodation of Dr. Auteri's religious exemption request, to undergo weekly testing for COVID-19 infection and to undergo daily health screenings, including daily temperature checks (the **"Auteri Accommodations"**). Exhibit "6" to the Second Amended Complaint (Second Exemption Request). By October 22, 2021, the CDC had admitted that the COVID-19 Vaccines did not stop transmission of the virus and in an email dated August 15, 2021, the Chief Medical Officer of Doylestown Health admitted the same (Document P-265).

Because COVID-19 vaccination had failed to stop transmission of SARS-CoV-2 as declared by the CDC and supported by multiple studies by August, 2021, and as admitted by Doylestown Health's executive representative Dr. Levy on August 15, 2021, an unvaccinated Dr. Autieri posed no undue or additional risk or harm to himself, hospital staff, or patients greater than that posed by Doylestown Health's vaccinated medical staff. Dr. Auteri was willing to undergo the Auteri Accommodations, but Doylestown Health's administration would not have any discussion about Dr. Auteri's proposed accommodations, refused to offer any alternate accommodation, and did not permit Dr. Auteri to continue his work as a cardiothoracic surgeon. Exhibit "6" to the Second Amended Complaint. Doylestown Health simply concluded that because Dr. Auteri was a

surgeon who treated a "vulnerable population," Dr. Auteri could not be safe in the care of patients. See transcript of deposition of B. Hebel[4], p. 14, l. 13-p. 15, l. 14; p. 17, l. 8-17; p. 27, l. 11-24. Ms. Hebel testified that Doylestown Health had a set of standard "accommodations" which did not take into account the actual health status of any specific care provider and used COVID-19 vaccination status as the arbiter of whether a specific care provider could treat patients at a level of "vulnerability" determined in some undisclosed way by Doylestown Health. See transcript of deposition of B. Hebel, p. 19, l. 12 – p. 20, l. 3; p. 22, l. 6 – p. 23, l. 2; p. 25, l. 20- p. 26, l. 10; see also transcript of J. Brexler,[5] at p. 146, l. 17 – p. 147, l. 14. Ms. Hebel testified that she did not use any data concerning transmission of the COVID-19 virus from any unvaccinated care provider to patients to determine whether or not to deny Dr. Auteri's accommodation request. See transcript of deposition of B. Hebel, p. 34, l. 14 – p. 35, l. 7. As discussed in detail above, Doylestown Health's reliance upon COVID-19 vaccination in the face of the facts known about those vaccines in the August through November 2021 timeframe was wholly deficient, not based in science, and resulted in an unsafe, elevated risk of COVID-19 virus transmission to vulnerable patients.

Multiple representatives of Doylestown Health's executive staff testified that Doylestown Health was NOT testing vaccinated members of the medical staff on a routine basis in that August through November 2021 timeframe in order to determine whether those medical staff members had the COVID-19 virus, despite Doylestown Health's

[4] References are to the transcript of the February 9, 2025 deposition of Barbara Hebel, Vice President, Human Resources.
[5] References are to the transcript of the February 17, 2025 deposition of James Brexler, President and Chief Executive Officer.

knowledge that vaccinated persons could harbor large viral loads in the nasopharynx and transmit SARS-CoV-2. See transcripts of depositions of J. Brexler, p. 135, l. 6-25; p. 136, l. 2-15; S. Levy[6], p. 136, l. 5-15, p. 159, l. 1-5. Ms. Hebel testified that Doylestown Health did not know which staff members were infected with COVID-19 on any given day, and Doylestown Health did not track the transmission of the virus from vaccinated staff members or health system employees to patients. See transcript of deposition of B. Hebel, p. 35, l. 6-13; p. 37, l. 10-17. Ms. Hebel also testified that for the period of August 2021 when Doylestown Health implemented the COVID-19 vaccine mandate through the date of Dr. Auteri's termination on November 18, 2021, Doylestown Health had no data which tracked transmission events nor had any reports of transmission of the COVID-19 virus from any Doylestown Health care provider or employee to a patient, and no evidence that Dr. Auteri transmitted the COVID-19 virus to anyone. See transcript of B. Hebel, p. 40, l. 24, p. 41, l. 11; p. 41, l. 13-20.

Dr. Levy testified that it was "certainly" a "possibility" that, in October 2021, a vaccinated doctor at Doylestown Health had COVID-19 and was treating patients. See transcript of deposition of S. Levy, p. 140, l. 9-13; see also transcript of deposition of J. Brexler, p. 137, l. 6-24. According to Dr. Levy, on any given day, there "absolutely" could be surgeons and doctors treating patients who had COVID-19 at that time. See transcript of deposition of S. Levy, p. 143, l. 10-13; p. 146, l. 7-10. In August through October 2021, Doylestown Health had no data showing that Dr. Auteri could transmit SARS-CoV-2 at a higher rate than a vaccinated provider. See transcript of deposition of S. Levy, p. 152, l. 16-24. Dr. Levy testified that in October 2021, only medical staff members demonstrating

[6] References are to the transcript of the February 13, 2025 deposition of Scott Levy, M.D. Chief Medical Officer.

significant symptoms of illness were being tested for the COVID-19 virus. See transcript of deposition of S. Levy, p. 136 at l. 5-15.

Had Dr. Auteri remained employed under the Auteri Accommodations, Dr. Auteri would have been safer in treating "vulnerable" patients than vaccinated medical staff members who were not working under the more strict Auteri Accommodations. As cited from the deposition testimony above, Doylestown Health was permitting vaccinated medical staff members to treat patients, including "vulnerable" patients, without testing unless those medical staff members were experiencing significant symptoms of illness and requested testing prompted by their symptoms. By early January 2022, approximately 6 weeks after Dr. Auteri's termination, Doylestown Health was permitting COVID-19 infected medical staff members to return to work without testing to determine the then-current presence of persistent SARS-CoV-2 in those staff members and whether those staff members still posed a threat to patients and coworkers. See Documents P-247-248 and P302-303.

As discussed above, COVID-19 vaccinated staff members could transmit the virus and to the extent that the vaccines were reducing symptoms, Doylestown Health's reliance upon the COVID-19 vaccines to determine "patient safety" likely made the spread of the virus worse by allowing continued virus transmission without any actual, "real time" knowledge of which medical staff members were infected and contagious. Under the Auteri Accommodations, Dr. Auteri offered to demonstrate on any given day that Dr. Auteri was not infected with SARS-CoV-2 and was safe to treat patients.

The Auteri Accommodations were not unduly burdensome to Doylestown Health in

terms of cost or administrative process. Had Doylestown Health discussed the Auteri Accommodations with Dr. Auteri, Doylestown Health could have required Dr. Auteri to pay for the testing, mandated more frequent testing, required offsite testing, etc. Doylestown Health admits that Doylestown Health did not discuss the possibility of Auteri Accommodations with Dr. Auteri at all. See transcript of deposition of B. Hebel, p. 43 at l. 2-10. At the time, Doylestown Health had not traced any case of COVID-19 virus transmission to Dr. Auteri. See transcript of deposition of S. Levy, p. 152 at l. 16-24; see also transcript of deposition of J. Brexler, p. 41 at l. 13-20. Doylestown Health did not have any internal data showing that Doylestown Health's unvaccinated medical staff providers were transmitting the COVID-19 virus at a greater rate than vaccinated medical staff providers. See transcripts of depositions of S. Levy, p. 148 at p. 13-21; J. Brexler, p. 37, l. 19 – p. 38, l. 7; B. Hebel, p. 34 at l. 14 – p. 35, l. 7. At the time of Dr. Auteri's termination, Doylestown Health had no evidence that Dr. Auteri posed a safety risk to patients or any greater risk of COVID-19 virus transmission than doctors who had undergone COVID-19 vaccination. The hospital administration's decision to terminate Dr. Auteri was without scientific merit nor grounded in solid public health policy. That decision was arbitrary, capricious, and was not in keeping with the standard of care provided by similar health systems across the country which allowed unvaccinated and vaccinated employees in the workplace. By the time of Dr. Auteri's termination on November 18, 2021, the COVID-19 vaccine campaign had failed and the vaccine status was irrelevant for surgeons such as Dr. Auteri.

III. CONCLUSION

In my expert medical opinion, within a reasonable degree of medical certainty, Dr. Auteri's concern that the COVID-19 vaccines were "genetic vaccines" was well founded in the known science and data at the time. It is also my expert medical opinion, which is within a reasonable degree of medical certainty, that the Auteri Accommodations would not have caused an undue burden on Doylestown Health. Doylestown Health's stated concerns about "patient safety" which resulted in Dr. Auteri's termination were not at all served by Doylestown Health's COVID-19 vaccine Mandate and related procedures. It is my expert medical opinion, which is within a reasonable degree of medical certainty, that Doylestown Health's procedures for allowing vaccinated medical staff members to work with patients without testing to provide "real time" knowledge of COVID-19 infection was not safe for patients and the Auteri Accommodations provided greater protection of patients, and that Doylestown Health knew or should have known that reliance upon COVID-19 vaccination was wholly insufficient to protect the "vulnerable" patient population which Doylestown Health claimed Dr. Auteri was unsafe to treat. Had Doylestown Health wanted to provide the best and most reasonable, efficient, and effective protection for patients from COVID-19, Doylestown Health would have followed the Auteri Accommodations or required more frequent testing. Dr. Auteri should not have received any pressure, coercion, or reprisal for requesting exemption from or declining COVID-19 vaccination.

Dr. Auteri's termination based upon his refusal to get vaccinated because of sincerely held religious beliefs was unlawful.

Dated:

Respectfully submitted,

/s/ Peter A. McCullough, M.D., MPH

Peter A. McCullough

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Exhibit E

April 9, 2025
Expert Report of Daniel Salmon, Ph.D., MPH

Professional Experience

Dr. Salmon is a Professor of Global Disease Epidemiology and Control, Department of International Health, Johns Hopkins University Bloomberg School of Public Health. He also has a joint appointment in the Department of Health, Behavior and Society. Dr. Salmon serves as the Director of the Institute for Vaccine Safety at Johns Hopkins.

Dr. Salmon is broadly trained in vaccinology, with an emphasis in epidemiology, behavioral epidemiology, and health policy. Dr. Salmon received a Bachelor of Arts (BA) in Political Science with a minor in Psychology from Rutgers University in 1991. He received a Master of Public Health (MPH) from Emory University Rollins School of Public Health in 1996. Dr. Salmon received a Doctor of Philosophy (PhD) from Johns Hopkins University Bloomberg School of Public Health in 2003.

Dr. Salmon has held positions in government and academia. Dr. Salmon has worked for the Centers for Disease Control and Prevention as a contractor and later as a Policy Analyst. In these positions, he used surveillance systems to conduct studies of measles and pertussis and coordinated Federal efforts around vaccine safety, immunization information systems, and development of new vaccines such as for tuberculosis. Dr. Salmon also served as the Director of Vaccine Safety, National Vaccine Program Office, Department of Health and Human Services. In this capacity, Dr. Salmon was responsible for coordinating and overseeing the nation's vaccine safety system including vaccine safety activities in the Department of Health and Human Services (National Institute of Health, Food and Drug Administration, Centers for Disease Control and Prevention, and Health Resources and Services Administration) other Federal Departments (Defense, Veterans Affairs, State), and non-federal partners including academia, industry, professional medical and public health associations, states and localities, and the public. Dr. Salmon led a Secretary's initiative in vaccine safety, oversaw the 2009 H1N1 vaccine safety program, and served as the Designated Federal Official for the National Vaccine Advisory Committee (NVAC) Vaccine Safety Working Group and the Advisory Commission on Childhood Vaccines (ACCV). Among other accomplishments, Dr. Salmon created the Post-Licensure Rapid Immunization Safety Monitoring (PRISM) Network to conduct active vaccine safety surveillance for the 2009 H1N1 immunization program. PRISM became an ongoing surveillance system for the Food and Drug Administration as a part of the Sentinel program.

Dr. Salmon has conducted a broad range of research in academia including research grants funded by the National Institutes of Health, Centers for Disease Control and Prevention, state health departments, the World Health Organization, Gavi, the Vaccine Alliance, the Robert Wood Johnson Foundation, and private industry including Walgreens, Pfizer, Merck and Crucell. Dr. Salmon has also served as a grant reviewer for the National Institutes for Health, Centers for Disease Control and Prevention, Food and Drug Administration, National Science Foundation, the Gates Foundation, as well as numerous other country federal health authorities. Dr. Salmon has taught and continues to teach a class in vaccine policy for two decades and also currently teaches a class in public health practice at Johns Hopkins University Bloomberg School of Public Health. Dr. Salmon has mentored numerous students and scientists, many of which now hold leadership positions in academia, government, and international organizations.

Dr. Salmon's research and practice work has included a broad range of studies examining the individual and community risks of vaccine refusal, the impact of laws and policies in increasing vaccination coverage and controlling vaccine preventable diseases, the reasons why patients and parents refuse vaccines, and the role of healthcare providers in impacting patient and parent vaccine decision-making. Dr. Salmon is widely considered a national and global expert in these areas. Dr. Salmon was a member of the Lancet Commission on Vaccine Hesitancy and served on a National Vaccine Advisory Committee Working Group on vaccine hesitancy.

Dr. Salmon has published more than 100 papers in top medical and public health journals including the New England Journal of Medicine, the Lancet, the Journal of the American Medical Association, Health Affairs, and Pediatrics. Dr. Salmon regularly serves as a peer reviewer for these and other high impact journals. He has been invited to give presentations at the National Foundation for Infectious Diseases, Federal advisory committees, and many international meetings. Dr. Salmon has served as an expert witness for a variety of legal cases. Dr. Salmon's current curriculum vitae is attached (Appendix 1).

Dr. Salmon has been retained by VIA Affiliates d/b/a Doylestown Health Physicians ("Doylestown Health"). Dr. Salmon has reviewed the following materials provided by Duane Morris LLP, on behalf of Doylestown Health:

1. Doylestown Health System Memorandum Re: COVID-19 Vaccination Mandate, August 6, 2021
2. COVID-19 Vaccines FAQ's transmitted on August 6, 2021 with Doylestown Health System Memorandum Re: COVID-19 Vaccination Mandate
3. Doylestown Hospital Occupational Health Services Immunization Policy, Review Date August 5, 2021
4. COVID-19 Vaccine Update, September 10, 2021
5. Doylestown Health Physicians (Medical Staff) COVID-19 Vaccine Mandate Announcement Email, August 6, 2021
6. Application for Religious Exemption For COVID-19 Vaccine
7. COVID Vaccination Documentation Requirement Email, August 13, 2021
8. COVID-19 Vaccine Requirement Email, August 30, 2021
9. Form of Letter Granting Exemption from COVID-19 Vaccination Mandate for Employees Remaining in Positions
10. Form of Letter Granting Exemption from COVID-19 Vaccination Mandate for Employees Reassigned to Different Positions
11. Managing DHS/Employees With COVID-19 Vaccine Exemption – Accommodation Strategies
12. List of Departments Reflecting Assessment of Patient Population Vulnerability for Each Department
13. Expert Report of Dr. Peter A. McCullough, MD, MPH

The client has not impacted the content of this report. All opinions herein are that of Dr. Salmon. Dr. Salmon has been compensated $20,000 for this report. Dr. Salmon will be

compensated at a rate of $450/hour for expert services rendered to Doylestown Health following completion of this expert report, including testimony at a deposition or trial.

Dr. Salmon was requested by the Defendant to provide opinions on the following issues:

Threats of COVID-19 to Patients and Healthcare Workers in November 2021

1. In November 2021, was COVID-19 a potentially fatal disease, particularly for vulnerable populations?

2. Are cardiac patients, particularly those undergoing cardiac surgery, more vulnerable to the threat of COVID-19 infection than other patients?

3. What are the risks of an unvaccinated person providing direct care, including surgery, to cardiac patients?

4. In November 2021, how did COVID-19 spread from person to person?

5. In November 2021, how did COVID-19 affect healthcare facilities, particularly with respect to patient access to care and quality of patient care?

6. In November 2021, what was the effect of asymptomatic transmission on the spread of COVID-19 on healthcare facilities?

7. In November 2021, how difficult was it for healthcare facilities to track the transmission of COVID-19 within the healthcare facility by vaccinated and/or unvaccinated persons, and would the data resulting from such tracking have been reliable?

8. Was exposure to COVID-19 an occupational hazard for employees of healthcare facilities?

9. Why were healthcare workers one of the first populations to receive the COVID-19 vaccine when it initially became available?

Safety and Efficacy of COVID-19 Vaccines

1. In November 2021, what was the efficacy of the available COVID-19 vaccines?

2. Does a COVID-19 vaccine that utilizes messenger ribonucleic acid (mRNA) have the effect of altering the genetic makeup of a person who receives such a vaccine?

3. Was the COVID-19 vaccine developed and manufactured by Janssen Biotech, Inc., an mRNA vaccine?

4. In November 2021, were unvaccinated persons, as compared to vaccinated persons, at an increased risk of becoming infected with COVID-19 and, therefore, transmitting the virus to others?

5. In November 2021, did available scientific evidence indicate that natural immunity (i.e., the presence of antibodies from prior infection) was as effective as vaccination to protect persons from COVID-19 infection?

6. In November 2021, was it possible to determine how long antibodies from prior COVID-19 infection could protect against subsequent COVID-19 infection?

7. In November 2021, did available scientific evidence indicate that antibodies from prior COVID-19 infection could protect persons against infection by a new strain of COVID-19?

Role of COVID-19 Vaccination Mandates in Managing Threats of COVID-19 to Patients and Healthcare Workers

1. In November 2021, did COVID-19 pose a direct threat to patients and healthcare workers?

2. In November 2021, were COVID-19 vaccination mandates a critical protection for patients and healthcare workers?

3. In November 2021, how effective were COVID-19 infection-control measures such as daily health questionnaires, temperature checks, and weekly testing, and were they sufficient safety measures in lieu of COVID-19 vaccination?

Effect of Non-Medical Exemptions From COVID-19 Vaccination Mandates

1. Did non-medical exemptions from COVID-19 vaccination mandates increase the risks of COVID-19 infection to patients and healthcare workers?

2. Did healthcare facilities have a responsibility to protect the safety of patients and staff by establishing and implementing processes for evaluating requests for exemption from COVID-19 vaccination mandates?

3. In evaluating requests for non-medical exemptions from COVID-19 vaccination mandates, was it appropriate to make distinctions between more vulnerable and less vulnerable patient populations for purposes of determining whether such a request could be accommodated?

Dr. Salmon's professional judgement in these areas is based upon review of current scientific evidence and federal advisory repots (referenced accordingly). However, at the request of counsel, data sources were limited to those available as of November 2021.

Threats of COVID-19 to Patients and Healthcare Workers in November 2021

In November 2021, was COVID-19 a potentially fatal disease, particularly for vulnerable populations?

COVID-19 was a very serious disease during this time as we were in the midst of a global pandemic with about 48 million cases of COVID-19 reported (November 15, 2021), about 35

million hospitalizations, and almost 760,000 deaths in the United States (U.S).[1] On November 15, 2021, the seven day average was about 95,000 cases, 48,000 hospitalizations, and 1,200 deaths. The CDC reported that 97% of hospitalizations and 99% of deaths were among unvaccinated persons in July, 2021.[2] Hospitalizations and deaths were disproportionately impacting the elderly and those with chronic medical conditions.[3] However, even some young and healthy individuals were experiencing serious disease, hospitalization and death. Vulnerable racial/ethnic populations (Black, Hispanic and Native American) were also disproportionately impacted by COVID-19.[4] The U.S. was experiencing the Delta (B.1.617.2) wave during this period. COVID-19 was appearing in waves and varied substantially by locality, state and region, as often is the case with infectious diseases.

Are cardiac patients, particularly those undergoing cardiac surgery, more vulnerable to the threat of COVID-19 infection than other patients?

It was well known in November 2021 that persons with cardiac disease were at increased risk for serious consequences from COVID-19. According to the American Heart Association in February, 2021: "Conditions such as heart failure (where the heart does not pump blood effectively), coronary artery disease (blocked arteries) and cardiomyopathies (weakening, thinning and/or thickening of the heart muscle) lead to more severe cases of COVID-19".[5] For these reasons, cardiac patients were particularly vulnerable to the health risks of COVID-19.

What are the risks of an unvaccinated person providing direct care, including surgery, to cardiac patients?

As discussed in greater detail below in connection with questions specifically about the risks of unvaccinated persons, an unvaccinated person was at increased risk of contracting and transmitting COVID-19 compared with a vaccinated person. Thus, an unvaccinated person providing direct care, including surgery, to cardiac patients was an increased risk to those cardiac patients compared to a vaccinated person providing direct care to cardiac patients. Given cardiac patients were among the high-risk groups for severe illness from COVID-19, the risk of unvaccinated persons providing care to this patient population was particularly high.

[1] Johns Hopkins Coronavirus Resource Center. https://coronavirus.jhu.edu/region/united-states accessed 03/23/25.
[2] CNN interview with Dr. Walensky, CDC Director. https://www.cnn.com/2021/07/19/health/us-coronavirus-monday/index.html accessed 03/22/25.
[3] Centers for Disease Control and Prevention. People with Certain Medial Conditions. https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html accessed 03/22/25.
[4] Don Bambino Geno Tai, Irene G. Sia, Chyke A. Doubeni, Mark L. Wieland. Disproportionate Impact of COVID-19 on Racial and Ethnic Minority Groups in the United States: a 2021 Update. J Racial Ethn Health Disparities. 2022; 9(6): 2334–2339.
[5] American Heart Association. https://www.heart.org/en/news/2021/02/11/heres-what-heart-patients-need-to-know-about-covid-19-in-2021 accessed 03/22/25.

In November 2021, how did COVID-19 spread from person to person?

It was well accepted among the scientific community at the time that COVID-19 spread person to person through respiratory droplets.[6] It was understood that the virus mainly spread between people in close contact with an infected person's mouth or nose when they cough, sneeze, speak, sing or breathe. This was particularly the case in indoor settings as aerosols could remain in the air. People could also be infected after touching surfaces or objects that had been contaminated with the virus.

In November 2021, how did COVID-19 affect healthcare facilities, particularly with respect to patient access to care and quality of patient care?

COVID-19 had a tremendous impact on healthcare systems, patient access to care and quality of care. As COVID-19 spread across the country in waves, disproportionately impacting some communities and then moving on to others, healthcare systems struggled to keep up with patient demand. Healthcare capacity in the United States is generally designed to meet demand, often with rural healthcare facilities below community needs. Consequently, the healthcare system was not well prepared for the surge of healthcare needs that resulted from COVID-19. The impact of COVID-19 on healthcare facilities was further strained by COVID-19 illness and death among healthcare workers and worker burnout.[7] Healthcare systems attempted to respond by establishing surge capacity, including portable morgues in hospitals for COVID-19 deaths. Additionally, healthcare providers and facilities delayed routine and non-emergency procedures to free up capacity to address heath care needs related to COVID-19.[8] The consequence was reduced access to care for patients and, in some cases, reductions in quality of care with increases in many diseases which were not diagnosed during routine care visits. The long-term impact of rationing healthcare because of the COVID-19 pandemic will take many years to fully characterize.

In November 2021, what was the effect of asymptomatic transmission on the spread of COVID-19 on healthcare facilities?

At this point, it was well accepted in the scientific community that asymptomatic persons were transmitting COVID-19.[9] Asymptomatic transmission of COVID-19 in healthcare facilities was a major problem through November 2021. Many healthcare facilities were regularly testing staff. However, such tests were imperfect and testing frequency limits the value of testing in detecting asymptomatic infections.[10]

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[6] Galbadage T, Peterson BM, Gunasekera RS. Does COVID-19 Spread Through Droplets Alone? Front Public Health. 2020 Apr 24;8:163.
[7] Wu H et al. National Healthcare Safety Network. Hospital capacities and shortages of healthcare resources among US hospitals during the coronavirus disease 2019 (COVID-19) pandemic, National Healthcare Safety Network (NHSN), March 27-July 14, 2020. Infect Control Hosp Epidemiol. 2022 Oct;43(10):1473-1476.
[8] The Rand Corporation. https://www.rand.org/content/dam/rand/pubs/research_briefs/RBA100/RBA164-1/RAND_RBA164-1.pdf accessed 03/22/24.
[9] Michael Johansson, Talia quandelacy, Sarah Kada et al. SARS-CoV-2 Transmission from People Without COVID-19 Symptoms. JAMA Netw Open. 2021;4(1):e2035057.
[10] Black JRM et al. COVID-19: the case for health-care worker screening to prevent hospital transmission. The Lancet. Volume 395, ISSUE 10234, P1418-1420, May 02, 2020.

In November 2021, how difficult was it for healthcare facilities to track the transmission of COVID-19 within the healthcare facility by vaccinated and/or unvaccinated persons, and would the data resulting from such tracking have been reliable?

It would be extremely difficult, labor intensive and costly for a healthcare facility to track the transmission of COVID-19 within a healthcare facility by vaccinated and/or unvaccinated persons. Additionally, doing so would require expertise not readily available to a healthcare facility, the data would be of poor quality, and it would take a lot of time further limiting the utility of such an endeavor as the virus would have likely mutated by the time the data were available.

For example, in July 2020 an article was published describing the investigation and management of a COVID-19 outbreak in Watford General Hospital, a 521-bed acute district general hospital situated in West Hertfordshire, U.K.[11] As described:

> SARS-CoV-2 outbreaks are difficult to recognise and control due to its high infectivity and the wide range of clinical manifestations of the infection…An outbreak control team (OCT) was convened…Root cause analyses (RCAs) were carried out on cases to identify possible causes, possible route of transmission and any learning points. All contact patients and staff were screened with RT PCR and genomic sequencing was performed on a set of positive specimens. In addition to active contact tracing, screening and cohorting of patients and staff, standard and transmission-based precautions were reinforced to control the outbreak…We recognised several challenges in investigating a COVID-19 outbreak in a hospital setting. Problems arising from variable sensitivity of the tests, difficulty in differentiating COVID-19 related symptoms from underlying diseases, problems related to establishing the route of transmission, issues with contact tracing.

If a healthcare facility were to track transmission, it would want to include identifying and implementing management processes so that there would be actionable information available to the healthcare facility. As described by the Centers for Medicare and Medicaid Services (CMS), root cause analysis is "a structured facilitated team process to identify root causes of an event that resulted in an undesired outcome and develop corrective actions. The RCA process provides you with a way to identify breakdowns in processes and systems that contributed to the event and how to prevent future events. The purpose of an RCA is to find out what happened, why it happened, and determine what changes need to be made."[12]

Once this entire process was complete, a hospital could then separate cases by vaccination status and try to ascertain chains of transmission (which would be very difficult and often inaccurate) to ascertain transmission by vaccination status. As a result, data from such tracking would not

[11] Kannangara CI, Seetulsingh P, Foley J, Bennett G, Carter T. Investigation and management of an outbreak of COVID-19 infection in an acute admission unit in a District General Hospital: lessons learnt. Infect Prev Pract. 2021 Sep;3(3):100156.

[12] CMS. https://www.cms.gov/medicare/provider-enrollment-and-certification/qapi/downloads/guidanceforrca.pdf accessed 03/23/25.

be very reliable and therefore not actionable. Additionally, conducting this sort of analysis would be very labor intensive and costly, multi-disciplinary expertise to do so would be beyond many healthcare facilities and it would take a substantial amount of time to design the study and then collect, analyze and interpret the data. This sort of study would typically be conducted by academic researchers.

Was exposure to COVID-19 an occupational hazard for employees of healthcare facilities?

Specific to employees of healthcare facilities, the Occupational Safety and Health Administration (OSHA), Department of Labor, provides the following definition of healthcare workers: "Healthcare workers (HCWs) are occupationally exposed to a variety of infectious diseases during the performance of their duties. The delivery of healthcare services requires a broad range of workers, such as physicians, nurses, technicians, clinical laboratory workers, first responders, building maintenance, security and administrative personnel, social workers, food service, housekeeping, and mortuary personnel."[13] From an epidemiological perspective, some healthcare workers may be at greater risk than others based on their job duties, particularly those who come into more direct patient contact. However, to prevent nosocomial infections and protect patients and healthcare workers, hospitals and other healthcare facilities must take a system wide approach focusing on all persons who may acquire and transmit disease.

Healthcare workers were at risk of occupational acquired COVID-19 through exposure to infected patients and other healthcare staff. Particularly concerning would be healthcare workers at increased risk of COVID-19 morbidity and mortality. The Advisory Committee on Immunization Practices (ACIP) of the CDC consequently prioritized healthcare workers for vaccination.[14] More than 3,600 healthcare workers died of COVID-19 in the first year of the pandemic.[15] The prevalence of SARS-CoV-2 infection among healthcare workers was 11% in 2020, noticeably higher than in the general population.[16] In a large healthcare system of about 30,000 employees between June 1 to December 31, 2020, 2,357 employees were involved in occupational COVID-19 exposures; 1,128 (48%) were exposed to patients and 1,229 (52%) to other employees.[17]

Why were healthcare workers one of the first populations to receive the COVID-19 vaccine when it initially became available?

The Advisory Committee on Immunization Practices (ACIP) and the Centers for Disease Control and Prevention (CDC) determined that healthcare personnel were the first priority for COVID-19 vaccine when it was available:

Phase 1a. Health care personnel (HCP) are being considered for phase 1a, which includes

[13] https://www.osha.gov/healthcare/infectious-diseases/ accessed 03/23/25.
[14] Bell BP, Romero JR , Lee GM. Scientific and ethical principles underlying recommendations from the advisory committee on immunization practices for COVID-19 vaccination implementation. *JAMA.* 2020; 324: 2025-2026
[15] KHN. 12 Months of Trauma: More Than 3,600 US Health Workers Died in Covid's First Year. https://khn.org/news/article/us-health-workers-deaths-covid-lost-on-the-frontline/ accessed 03/23/25.
[16] Sergio Alejandro Gómez-Ochoa et al. COVID-19 in Healthcare Workers: A Living Systematic Review and Meta-analysis of Prevalence, Risk Factors, Clinical Characteristics, and Outcomes. Am J Epidemiol. 2020 Sep 1.
[17] Jessica Ibiebele, Christina Silkaitis, Gina Dolgin et al. Occupational COVID-19 exposures and secondary cases among healthcare personnel. Am J Infect Control. 2021 Oct; 49(10): 1334–1336.

> the first available doses and an extremely constrained supply. HCP are defined as all paid and unpaid persons serving in health care settings who have the potential for direct or indirect exposure to patients or infectious materials, comprising an estimated 20 million people. Examples include hospital, long-term care and assisted living, home health care, and outpatient facility staff, as well as pharmacies and emergency medical services. HCP are essential for the ongoing COVID-19 response and are at high risk for exposure to SARS-CoV-2.[18]

Healthcare personnel were the first priority for initial availability of COVID-19 vaccines for several reasons:

1) Healthcare personnel were at increased risk of contracting and transmitting COVID-19 because of their occupational exposure to COVID-19 cases;
2) Healthcare personnel were in regular contact with persons at increased risk of serious complications and death from COVID-19, including persons who were immunocompromised, had other comorbidities, and/or were elderly; and
3) Healthcare facilities were often at or beyond capacity caring for persons with COVID-19 as well as other healthcare needs. As essential personnel, reducing the risk of healthcare personnel contracting COVID-19 resulting in missed time from work and potentially morbidity and mortality was a local, state and national priority in order to maintain healthcare capacity; and
4) Given the sacrifice healthcare personnel were making to care for COVID-19 infected persons in addition to persons requiring other healthcare needs, it was equitable for personnel to receive all means available to protect themselves from COVID-19.

Safety and Efficacy of COVID-19 Vaccines

In November 2021, what was the efficacy of the available COVID-19 vaccines?

In November of 2021, three vaccines were available:
1) Moderna COVID-19 vaccine (mRNA-1273);
2) Pfizer and BioNTech COVID-19 vaccine (BNT162b2); and
3) Janssen Biotech COVID-19 vaccine (Ad26.COV2.S)

The most accurate estimates of the efficacy of COVID-19 vaccines at the time were based on the information available from the phase 3 clinical trials that were consider by the Food and Drug Administration (FDA) and its Vaccines and Related Biological Product Advisory Committee (VRBPAC), which were made available to the public.

The Moderna COVID-19 vaccine (mRNA-1273) was authorized for use to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The Phase 3 randomized, double-blinded and placebo-controlled trial of mRNA-1273 included approximately 30,400 participants. The primary efficacy endpoint was the reduction of incidence of COVID-19 among participants without evidence of SARS-CoV-2 infection before the first dose of vaccine.

[18] Bell BP, Romero JR , Lee GM. Scientific and ethical principles underlying recommendations from the advisory committee on immunization practices for COVID-19 vaccination implementation. *JAMA.* 2020; 324: 2025-2026

Efficacy in preventing confirmed COVID-19 occurring at least 14 days after the second dose of vaccine was 94.5.0% (95% CI 86.5%, 97.8%). Subgroup analyses showed similar efficacy across age groups, genders, racial and ethnic groups, and participants with medical comorbidities associated with high risk of severe COVID-19.[19]

The Pfizer and BioNTech COVID-19 vaccine (BNT162b2) was authorized for use to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The Phase 3 randomized, double-blinded and placebo-controlled trial of BNT162b2 included approximately 44,000 participants. The primary efficacy endpoint was incidence of COVID-19 among participants without evidence of SARS-CoV-2 infection before or during the 2-dose vaccination regimen. Efficacy in preventing confirmed COVID-19 occurring at least 7 days after the second dose of vaccine was 95.0%. Subgroup analyses showed similar efficacy across age groups, genders, racial and ethnic groups, and participants with medical comorbidities associated with high risk of severe COVID-19.[20]

Janssen Biotech COVID-19 vaccine (Ad26.COV2.S) was authorized for use to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The Phase 3 randomized, double-blind and placebo-controlled trial of Ad26.COV2.S included approximately 40,000 participants. Vaccine efficacy against central laboratory-confirmed moderate to severe/critical COVID-19 was 66.9% (95% CI 59.0, 73.4) when considering cases occurring at least 14 days after the single-dose vaccination. Subgroup analyses showed similar efficacy across age groups, genders, racial and ethnic groups, and participants with medical comorbidities associated with high risk of severe COVID-19.[21]

The Delta variant was the most dominant strain in November 2021. It was widely accepted in the scientific community that the Delta variant had higher transmissibility and was responsible for the majority of illness, hospitalization and death in the US. Cases of COVID were reported among vaccinated persons (breakthrough cases) and there were indications that the vaccines were not as effective as previously characterized. The decrease in effectiveness may have been due to waning immunity of the vaccine (protection goes down over time) or because of differences in strain (Delta).

The most recent and highest quality data examining the effectiveness of vaccines, published by the CDC on August 27, 2021, was real world or observational data among frontline workers between December 14, 2020–August 14, 2021. [22]

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[19] Vaccines and Related Biological Products Advisory Committee Meeting. December 17, 2020. FDA Briefing Document. Moderna COVID-19 Vaccine. https://www.fda.gov/media/144434/download Accessed 03/23/2025.
[20] Vaccines and Related Biological Products Advisory Committee Meeting. December 10, 2020. FDA Briefing Document. Pfizer-BioNTech COVID-19 Vaccine. https://www.fda.gov/media/144245/download Accessed 03/23/2025.
[21] Vaccines and Related Biological Products Advisory Committee Meeting
February 26, 2021 FDA Briefing Document: Janssen Ad26.COV2.S Vaccine for the Prevention of COVID-19. https://www.fda.gov/media/146217/download. Accessed 03/23/2025.
[22] Centers for Disease Control and Prevention. Effectiveness of COVID-19 Vaccines in Preventing SARS-CoV-2 Infection Among Frontline Workers Before and During B.1.617.2 (Delta) Variant Predominance — Eight U.S. Locations, December 2020–August 2021. MMWR. August 27, 2021 / 70(34);1167-1169.

Regarding waning immunity, the CDC reported: "Adjusted VE against SARS-CoV-2 infection was 80% (95% confidence interval [CI] = 69%–88%). The VE point estimate was 85% among participants for whom <120 days had elapsed since completion of full vaccination compared with 73% among those for whom ≥150 days had elapsed; however the VE 95% CI were overlapping, indicating the difference was not statistically significant."

When focusing exclusively on the Delta variant, the CDC reported the following:

> During December 14, 2020–August 14, 2021, full vaccination with COVID-19 vaccines was 80% effective in preventing RT-PCR–confirmed SARS-CoV-2 infection among frontline workers, further affirming the highly protective benefit of full vaccination up to and through the most recent summer U.S. COVID-19 pandemic waves. The VE point estimates declined from 91% before predominance of the SARS-CoV-2 Delta variant to 66% since the SARS-CoV-2 Delta variant became predominant at the HEROES-RECOVER cohort study sites; however, this trend should be interpreted with caution because VE might also be declining as time since vaccination increases and because of poor precision in estimates due to limited number of weeks of observation and few infections among participants.

From these data and other similar limited and preliminary results in the scientific literature, it was clear that the vaccine was still very beneficial in preventing disease and consequent disease transmission. Concerns about waning immunity led to consideration of and ultimately recommendations for a booster doses.

Does a COVID-19 vaccine that utilizes messenger ribonucleic acid (mRNA) have the effect of altering the genetic makeup of a person who receives such a vaccine?

No, mRNA COVID-19 vaccines could not change someone's DNA (genetic makeup). As described by the National Human Genome Research Institute of the National Institute of Health at the time (August 30, 2021): "mRNA vaccines inject cells with instructions to generate a protein that is normally found on the surface of SARS-CoV-2, the virus that causes COVID-19…. mRNA vaccines are safe and cannot alter your DNA".[23] It was widely accepted among the scientific community that mRNA vaccines could not alter DNA.

Was the COVID-19 vaccine developed and manufactured by Janssen Biotech, Inc., an mRNA vaccine?

No, Janssen Biotech COVID-19 vaccine was not an mRNA vaccine. The Janssen vaccine was a viral (adenovirus) vector vaccine. Other viral vector vaccines include Japanese encephalitis, Lassa fever, Ebola, hepatitis B, hepatitis E and malaria.

In November 2021, were unvaccinated persons, as compared to vaccinated persons, at an increased risk of becoming infected with COVID-19 and, therefore, transmitting the virus to others?

[23] National Human Genome Research Institute of the National Institute of Health. https://www.genome.gov/about-genomics/fact-sheets/Understanding-COVID-19-mRNA-Vaccines accessed 03/23/25.

Given the benefits of COVID-19 vaccines in reducing disease acquisition and transmission, unvaccinated persons were at an increased risk of contracting COVID-19 and transmitting it to others, including through meeting in person with fellow employees and patients, who could not be vaccinated because of medical contraindications as well as persons who were vaccinated but the vaccine did not sufficiently work for them (the vaccines were not 100% effective, see earlier discussion). The protection afforded by COVID-19 vaccines, like all vaccines, is not perfect so it was known that a vaccinated person could transmit disease. However, because the vaccines reduced the likelihood of infection, they also reduced the likelihood of transmission of disease to others. It was difficult to perfectly predict the reduced likelihood of disease transmission in vaccinated versus unvaccinated persons, particularly during a pandemic with evolving knowledge of the disease and uncertainty around mutations. Additionally, because experience with the vaccine was limited the potential for protection from the vaccine to wane over time was not well understood. Despite these limitations, it was widely accepted in the scientific community that COVID-19 vaccines reduced the likelihood of disease transmission and consequently unvaccinated persons were at increased risk of disease transmission.

In November 2021, did available scientific evidence indicate that natural immunity (i.e., the presence of antibodies from prior infection) was as effective as vaccination to protect persons from COVID-19 infection?

Several studies were available at that time that indicated an immune response to COVID-19 that lasted for at least a short time,[24, 25,26] reduced the risk of reinfection, [27] and infections provided some level of protection among Rhesus monkeys.[28] However, good correlates of protection were not available. A correlate of protection is a set of "empirically defined, quantifiable immune parameters that determine the attainment of protection against a given pathogen."[29] In other words, it was not known what sort or type of immune response or how strong an immune response was necessary to protect from COVID-19, including but not limited to new variants that might emerge. So, although it was measured that natural infection resulted in an immune response which lasted at least for months, it was not known if that immune response protected against COVID-19. Additionally, while there was some indication that infection reduced the risk of reinfection, there was not a good measure of how much it reduced reinfection nor for how long. A CDC study available in August of 2021 indicated that among previously infected persons, reinfection was about twice as high if not being fully vaccinated, leading CDC to recommend "To reduce their likelihood for future infection, all eligible persons should be

[24] Staines HM, Kirwan DE, Clark DJ, et al. IgG seroconversion and pathophysiology in severe acute respiratory syndrome coronavirus 2 infection. Emerg Infect Dis. 2021 Jan;27.
[25] Wajnberg A, Amanat F, Firpo A, et al. Robust neutralizing antibodies to SARS-CoV-2 infection persist for months. Science. 2020 Dec;370(6521):1227-1230.
[26] Dan JM, Mateus J, Kato Y, et al. Immunological memory to SARS-CoV-2 assessed for up to 8 months after infection. Science. 2021 Feb 5;371(6529):eabf4063.
[27] Gallais F, Gantner P, Bruel T, et al. Anti-SARS-CoV-2 Antibodies Persist for up to 13 Months and Reduce Risk of Reinfection. medRxiv. 2021.
[28] Bao L, Deng W, Gao H, et al. Lack of Reinfection in Rhesus Macaques Infected with SARS-CoV-2. bioRxiv. 2020.
[29] Altmann DM, Douek DC, Boyton RJ. What policy makers need to know about COVID-19 protective immunity. The Lancet. 2020 May;395(10236):1527–1529.

offered COVID-19 vaccine, even those with previous SARS-CoV-2 infection."[30] Natural immunity also comes with the potential for morbidity and mortality from COVID-19. Monitoring of healthy individuals for more than 35 years had shown that reinfection with the same seasonal coronavirus occurred frequently[31] and protection from seasonal coronavirus infections are short lived.[32]

In November 2021, was it possible to determine how long antibodies from prior COVID-19 infection could protect against subsequent COVID-19 infection?

In November 2021 there was not scientific consensus on how long prior COVID-19 infection would protect against subsequent COVID-19 infection.

In November 2021, did available scientific evidence indicate that antibodies from prior COVID-19 infection could protect persons against infection by a new strain of COVID-19?

In November 2021, available scientific evidence could not predict if antibodies from prior COVID-19 infection would protect against infection by a new strain of COVID-19. The virus was mutating in unpredictable ways domestically and globally. Scientists were struggling to keep track of these mutations and determining which mutation would become dominant. Additionally, not knowing what the new strain would be it was impossible to ascertain if prior infection from a previous infection would protect against a new strain.

Role of COVID-19 Vaccination Mandates in Managing Threats of COVID-19 to Patients and Healthcare Workers

In November 2021, did COVID-19 pose a direct threat to patients and healthcare workers?

In November 2021, COVID-19 posed a direct threat to patients and staff in healthcare facilities. Healthcare facilities around the country and the world were being overwhelmed by COVID-19. Healthcare staff were disproportionately impacted by COVID-19. Additionally, patients in healthcare facilities were at substantial risk of exposure to and infection with COVID-19 despite precautionary measures that were taken to reduce the risk of transmission in healthcare settings. Often, patients in healthcare settings were at increased risk of severe COVID-19 because of underlying health conditions and age.

In November 2021, were COVID-19 vaccination mandates a critical protection for patients and healthcare workers?

Mandatory COVID-19 vaccination policies for healthcare employees were a critical protective action at this time to protect patients and staff. As discussed, COVID-19 posed a direct threat to

[30] Centers for Disease Control and Prevention. Reduced Risk of Reinfection with SARS-CoV-2 After COVID-19 Vaccination — Kentucky, May–June 2021. MMWR. August 13, 2021 / 70(32);1081-1083.
[31] Om E, Byrne P, Walsh KA, et al. Immune response following infection with SARS-CoV-2 and other coronaviruses: A rapid review. Rev Med Virol. 2021 Mar;31(2):e2162.
[32] Edridge AWD, Kaczorowska J, Hoste ACR, et al. Seasonal coronavirus protective immunity is short-lasting. Nat Med. 2020 Nov;26(11):1691–1693.

patients and staff in healthcare settings. Healthcare facilities around the country and the world were being overwhelmed by COVID-19. Healthcare staff were disproportionately impacted by COVID-19. Additionally, patients were at substantial risk of exposure and infection with COVID-19 despite precautionary measures that were taken to reduce the risk of transmission.[33]
Mandatory COVID-19 vaccine policies were a critical protective action to protect patients and staff for the following reasons:

1) COVID-19 posed a substantial threat to patients and staff;
2) COVID-19 vaccines provided a high level of protection against contracting COVID-19 and reducing transmission of COVID-19; and
3) Mandatory vaccination policies for influenza vaccines in healthcare settings have been demonstrated to be necessary to achieve high levels of vaccine coverage (voluntary policies even coupled with free access to vaccines and education did not achieve very high levels of vaccine coverage).

Mandatory COVID-19 vaccine policies were directly related to and often drew from mandatory influenza vaccine policies that have long been very important for healthcare institutions. Mandatory influenza vaccine policies are very important for healthcare institutions and directly relate to mandatory COVID-19 vaccine policies. Exposure to influenza in healthcare settings is an occupational hazard. Asymptomatic and healthcare workers who come to work ill (including the day before symptoms become apparent and the person is infectious) can transmit influenza to patients. Likewise, patients may be asymptomatic and transmitting influenza, including to unvaccinated healthcare workers and other patients. There is a broad range of strategies to reduce the risk of influenza among healthcare workers and protect patients who come into contact with such personnel. Strategies to reduce the risk of influenza in healthcare institutions include offering education and free, on-site vaccination, implementation of hand and respiratory hygiene and cough etiquette, screening and isolation of healthcare workers and patients with acute respiratory infections, and other prevention measures.[34]

Influenza vaccination is the most effective strategy to protect healthcare workers from contracting influenza and transmitting it to their patients. Vaccination of healthcare workers has been shown to be very effective, with minimal adverse effects, and shown to reduce patient mortality. [35] Despite considerable efforts at the Federal level and among states, with strong support from medical associations, influenza vaccination coverage among healthcare workers remains suboptimal.

Many healthcare institutions require influenza vaccination among their workers to protect their employees and the patients they care for. The Society for Healthcare Epidemiology of America (SHEA) strongly endorses mandatory vaccination of healthcare workers to protect against influenza, as can be seen in their most recent policy position on this topic:

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[33] Du Q et al. Nosocomial infection of COVID-19: A new challenge for healthcare professionals (Review). Int J Mol Med. 2021 Apr;47(4):31. doi: 10.3892/ijmm.2021.4864. Epub 2021 Feb 4.
[34] CDC. Prevention Strategies for Seasonal Influenza in Healthcare Settings. [cited 2011 17 November]; Available from: http://www.cdc.gov/flu/professionals/infectioncontrol/healthcaresettings.htm. accessed 03/23/25.
[35] Burls A, Jordan R, Barton P et al. Vaccinating healthcare workers against influenza to protect the vulnerable – is it. A good use of healthcare resources? A systematic review of the evidence and an economic evaluation. Vaccine. 2006. May 8; 24(19): 4212-21.

> SHEA views influenza vaccination of HCP as a *core patient and HCP safety practice* with which noncompliance should not be tolerated. It is the professional and ethical responsibility of HCP and the institutions within which they work to prevent the spread of infectious pathogens to their patients through evidence-based infection prevention practices, including influenza vaccination. *Therefore, for the safety of both patients and HCP, SHEA endorses a policy in which annual influenza vaccination is a condition of both initial and continued HCP employment and/or professional privileges.*[36]

Many professional medical and public health associations also support mandatory influenza vaccination of healthcare workers, including the American Academy of Family Physicians, the American Academy of Pediatrics, the American College of Physicians, the American Hospital Association, the American Medical Directors Association, the American Nurses Association, the American Public Health Association, the Association for Professionals in Infection Control and Epidemiology, the Infectious Disease Society of America, the National Association of County and City Health Officials, National Patient Safety Foundation, and others.[37]

This experience with influenza vaccine mandates in healthcare settings is directly applicable to COVID-19 mandates in healthcare settings. As with influenza, COVID-19 exposure in healthcare settings is an occupational hazard. Asymptomatic healthcare workers who come to work ill (including the day before symptoms become apparent and the person is infectious) can transmit COVID-19 to patients. Likewise, patients may be asymptomatic and transmitting COVID-19, including to unvaccinated healthcare workers and other patients. Voluntary programs for COVID-19 vaccination even coupled with access and education, as is the case with influenza, were unlikely to adequately reach very high levels of vaccine coverage necessary for protecting healthcare workers and patients. For example, we conducted a survey in late 2020 before the vaccines were available at SUNY Upstate Medical University in Syracuse, NY, the only academic medical center in Central New York and the region's largest employer with 9,565 employees.[38] We found that 57.5% of individuals expressed intent to receive COVID-19 vaccine, including 80.4% of physicians and scientists. Nearly half or more of nurses, Master's level clinicians, allied health professionals, and ancillary service personnel were not sure whether the vaccine would work and protect them from COVID-19; slightly lower but similar levels of uncertainty were expressed by the same groups about vaccine safety, and nearly a third of each group was unsure whether they would take a vaccine for COVID-19 if offered for free. The attitudes and concerns of nurses were very similar to those of the general public at the time. We conducted a follow-up survey in this healthcare system between 21 February and 19 March 2021 and found that 87.7% of respondents had already received a COVID-19 vaccine or planned to get vaccinated.[39] Physicians and scientists

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[36] Revised SHEA position paper: influenza vaccination of healthcare personnel. Infection Control and Hospital Epidemiology. Oct 2010. 31(10); 987-995.

[37] See https://www.immunize.org/honor-roll/influenza-mandates/ for list of these organizations that have policy positions supporting mandatory influenza vaccination for healthcare workers, including links to these policy statements. Accessed 03/23/25.

[38] Jana Shaw, Telisa Steward, Kathryn Anderson, Samantha Hanley, Stephen Thomas, Daniel Salmon, Christopher Morley. Assessment of U.S. health care personnel (HCP) attitudes towards COVID-19 vaccination in a large university health care system. Clin Infect Dis. 2021 Jan 25.

[39] Jana Shaw, Samantha Hanley, Telisa Steward, Daniel Salmon, Christin Ortiz, Paula Trief, Elizabeth Reddy, Christopher Morley, Stephen Thomas, Kathryn Anderson. Healthcare Personnel (HCP) Attitudes About

showed the highest acceptance rate (97.3%), whereas staff in ancillary services showed the lowest acceptance rate (79.9%). These levels of COVID-19 vaccine coverage were too low to provide adequate protection, leading New York to require vaccination of healthcare workers in September of 2021 and experiencing a 10% increase in vaccine coverage within a week.[40]

Similarly, many healthcare systems and medical providers were finding voluntary programs for COVID-19 vaccination to be insufficient and were thus turning to mandatory programs. According to the COVID States Project, as of July 2021, 27% of healthcare workers were unvaccinated and 15% were vaccine resistant, leading the authors to conclude that "absent mandates, most of the currently unvaccinated healthcare workers will remain unvaccinated, potentially fueling outbreaks in health care facilities."[41] A joint statement by 88 major medical organizations and associations called for mandatory vaccination of healthcare workers, including the American Hospital Association, the American Medical Association, the American College of Physicians, the American Academy of Family Physicians, and the American Public Health Association.[41,42] In August, 2021, the Department of Veterans Affairs announced that all employees and staff at VA facilities had to be vaccinated for COVID-19.[43] On September 9, 2021, President Biden announced a requirement for all healthcare workers working in settings that receive Medicare or Medicaid reimbursement to receive COVID-19 vaccines.[44]

In November 2021, how effective were COVID-19 infection-control measures such as daily health questionnaires, temperature checks, and weekly testing, and were they sufficient safety measures in lieu of COVID-19 vaccination?

Daily health questionnaires, temperature checks and weekly testing were not sufficient safety measures in lieu of vaccination. Health questionnaires are self-reported data, which are notoriously inaccurate. However, even if the person completing the questionnaire is perfectly accurate in their responses, as is largely the case with temperature checks (not self-reported), at best these approaches might be an indication that a test was warranted. However, by November of 2021, it had been well established that people could transmit COVID-19 before becoming symptomatic and among asymptomatic cases.

Regular testing for COVID-19 may allow for the identification of persons who have active disease. However, there are limitations to this approach. First, available COVID-19 tests are

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Coronavirus Disease 2019 (COVID-19) Vaccination After Emergency Use Authorization. Clin Infect Dis. 2022 Aug 24;75(1):e814-e821.

[40] Forbes. Covid-19 Vaccine Mandates Are Working—Here's The Proof https://www.forbes.com/sites/tommybeer/2021/10/04/covid-19-vaccine-mandates-are-working-heres-the-proof/?sh=8555e4b23058 accessed 03/23/25.

[41] Lazer David, et al. The COVID States Project #62: COVID-19 vaccine attitudes among healthcare workers. The COVID States Project. Aug 18, 2021

[42] Joint Statement in Support of COVID-19 Vaccine Mandates for All Workers in Health and Long-Term Care. https://assets.acponline.org/acp_policy/statements/joint_statement_covid_vaccine_mandate_2021.pdf accessed 03/23/25.

[43] US Department of Veteran Affairs. VA mandates COVID-19 vaccines among its medical employees including VHA facilities staff. https://www.va.gov/opa/pressrel/pressrelease.cfm?id=5696 accessed 03/23/25.

[44] The White House. Remarks by President Biden on Fighting the COVID-19 Pandemic https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/09/09/remarks-by-president-biden-on-fighting-the-covid-19-pandemic-3/ accessed 03/23/25.

imperfect with the potential for both false positives and false negatives. Second, weekly COVID-19 testing would not identify people as soon as they became infectious, potentially allowing someone to transmit COVID-19 for up to a week before testing positive. Even daily testing would still miss cases transmitting disease between tests. Regardless of testing interval, in the time between when a person first became infectious and when the test was taken there was risk that the person would infect others.

Effect of Non-Medical Exemptions From COVID-19 Vaccination Mandates

Did non-medical exemptions from COVID-19 vaccination mandates increase the risks of COVID-19 infection to patients and healthcare workers?

Unvaccinated persons (those with medical and non-medical exemptions) are at increased risk of contracting disease and transmitting disease to unvaccinated individuals (including, but not limited to, others who cannot be vaccinated because of medical contraindications or who are too young to be vaccinated), and to vaccinated individuals for whom the vaccine did not work (no vaccine is 100% effective). The impact of non-medical exemptions has been extensively studied among children for pertussis and measles, though the epidemiological principles apply to influenza vaccine and non-medical exemptions among healthcare workers. Children who have non-medical exemptions are 22-35 times more likely to contract measles and 6 times more likely to contract pertussis than vaccinated children.[45,46] In addition to this individual risk, exempt persons also increase the risk to others. Studies we have conducted demonstrate that communities with higher rates of non-medical exemptions are at increased risk of pertussis outbreaks.[45,46,47] We also found that states that had easier non-medical exemptions processes for granting exemptions had higher rates of non-medical exemptions and higher rates of pertussis.[48,49]

Measles also highlights the community risks of vaccine refusal.[50] Measles has been eliminated in the United States because of sustained high coverage of a very safe and effective vaccine. However, there are communities in the United States with high rates of vaccine refusal and measles is still circulating in many parts of the world. As a result, measles is introduced into these communities with high rates of vaccine refusal – clustered socially or geographically –

[45] Salmon DA, Haber M, Gangarosa EJ, Phillips L, Smith N, Chen RT. Health consequences of religious and philosophical exemptions from immunization laws: individual and societal risks of measles. JAMA. 1999 July 7; 282(1): 47-53.
[46] Feikin DR, Lezotte DC, Hamman RF, Salmon DA**,** Chen RT, Hoffman RE. Individual and community risks of measles and pertussis associated with personal exemptions to immunizations. JAMA. 2000 Dec. 27; 284(24): 3145-3150.
[47] Atwell JE, Van Otterloo J, Zipprich J, Winter K, Harriman K, Salmon DA, Halsey NA, Omer SB. Nonmedical vaccine exemptions and pertussis in California, 2010. Pediatrics. 2013 Oct;132(4):624-30.
[48] Rota JS, Salmon DA, Rodewald LE, Chen RT, Hibbs BF, Gangarosa EJ. Processes for obtaining nonmedical exemptions to state immunization laws. AJPH. April 2000; 91: 645-8.
[49] Omer SB, Pan WK, Halsey NA, Stokely S, Moulton LH, Navar AM, Salmon DA. Nonmedical Exemptions to School Immunization Requirements: Secular Trends and Association of State Policies with Pertussis Incidence. JAMA. 2006 Oct 11; 296(14):1757-63.
[50] Salmon DA, Dudley MZ*, Glanz JM, Omer SB. Vaccine hesitancy: Causes, consequences, and a call to action. Co-Published. Vaccine & Am J Prev Med. 2015 Nov 23; Suppl 4:D66-71.

resulting in outbreaks of measles.[51] An outbreak originating in Disneyland in 2015 caught the most national attention though there have been similar outbreaks in the Somali community in Minnesota and orthodox Jewish community in New York. As a result, the United States almost lost its "elimination status" in 2009, the same year that the World Health Organization declared vaccine hesitancy a top 10 global health threat. Several states (California, New York, Maine and Washington) have consequently eliminated their non-medical exemptions (Washington only eliminated non-medical exemptions for the MMR vaccine). There was recently a case of paralytic polio in the same orthodox Jewish community in New York which had the measles outbreak. This single case of polio indicates there are likely thousands of cases of asymptomatic polio in the community given the often-asymptomatic nature of polio. Sewage samples testing positive for polio support this.

These studies have been focused on children because every state has laws requiring vaccination for school entry. These studies have focused on measles and pertussis because the epidemiology of the diseases makes them well suited for such studies. However, the findings from these studies are very generalizable to non-medical exemptions to COVID-19 vaccine requirements for healthcare workers given the nature of infectious diseases and the impact of unvaccinated persons with exemptions. In fact, the impact of exemptions for COVID-19 vaccine among healthcare workers would be much higher than in the case with childhood vaccines because healthcare workers regularly come into contact with patients who are at increased risk for COVID-19 complications and death.

Did healthcare facilities have a responsibility to protect the safety of patients and staff by establishing and implementing processes for evaluating requests for exemption from COVID-19 vaccination mandates?

Exemptions to COVID-19 vaccine requirements had the potential to undermine vaccine requirements, particularly if a large number of exemptions were granted. However, many COVID-19 vaccine requirements were implemented in such a way that exemptions were either not granted or only a small number of exemptions were granted, and in such situations, there were substantial increases in vaccine coverage and a small number of persons who left employment because of the mandates. Many healthcare institutions that instituted mandates offered medical exemptions for those with valid medical contraindications and religious exemptions. Even if medical exemptions met guidelines for contraindications or religious exemptions were determined to be sincere, many healthcare institutions determined that the risks to others imposed an undue burden and, consequently, did not grant some or all exemption requests.

As previously described, each non-medical exemption a healthcare facility granted increased the risk of COVID-19 disease transmission and outbreaks adversely impacting other healthcare staff, patients, and the capacity of the healthcare system to operate. One can reasonably conclude that exemptions would be geographically clustered, increasing their impact, given COVID-19 vaccine hesitancy had been shown to geographically cluster and healthcare workers tended to live in the communities in which they work.

[51] Phadke VK. Bednarczyk RA, Salmon DA, Omer SB. Association between Vaccine Refusal and Vaccine Preventable Diseases in the United States: A Focus on Measles and Pertussis. JAMA. 2016 Mar; 315(11): 1149-58.

In evaluating requests for non-medical exemptions from COVID-19 vaccination mandates, was it appropriate to make distinctions between more vulnerable and less vulnerable patient populations for purposes of determining whether such a request could be accommodated?

It was appropriate, based upon available scientific evidence, to make distinctions between more vulnerable and less vulnerable patients for the purpose of evaluating exemption requests. As described, unvaccinated (exempt) staff were at increased risk of contracting and transmitting COVID-19 compared with vaccinated staff. The increased risk of unvaccinated (exempt) staff compared to vaccinated staff included the risk of transmission to other staff and patients. Many patients in this setting were at increased risk of severe disease, while other patients were not at increased risk of severe disease. Of particular concern was the increased risk of unvaccinated (exempt) staff to patients at increased risk of severe disease. At this time, subpopulations at increased risk of severe disease (such as those with cardiac disease) were well characterized. Requiring unvaccinated (exempt) staff to only work with less-vulnerable patients was based upon well accepted science at the time and could be expected to reduce or mitigate the risk of unvaccinated (exempt) staff.

Conclusion

In summary, in November 2021 the world was amid a global pandemic with the United States experiencing a large number of cases and substantial morbidity and mortality. Certain subpopulations such as the elderly and persons with underlying health conditions, such as cardiac patients, were at substantial increased risk of more severe disease and death if they contracted COVID-19. Healthcare institutions were particularly hard hit by COVID-19, experiencing high rates of disease and struggling to meet patient needs given limited capacity. Unvaccinated healthcare workers were at increased risk of contracting and transmitting COVID-19.

At the time, it was well accepted in the scientific and medical communities that COVID-19 was spread from person to person and people could asymptomatically transmit disease. It would have been extremely difficult for a healthcare facility to track transmission by vaccination status and any such efforts would not have yielded reliable and actionable information.

COVID-19 was an occupational hazard and, for all the foregoing reasons, healthcare workers were prioritized by the CDC to be among the first to receive the vaccine. Three vaccines were available at the time, and they were found to be very safe and effective. While there was indication that there was some level of natural immunity post infection, it was unclear how effective and for how long natural infection would provide protection and there was no evidence to indicate how well natural infection would protect against the next variant. Because of the risk of COVID-19 transmission from unvaccinated healthcare workers to high-risk patients and suboptimal voluntary vaccine acceptance among healthcare workers, and following the model of influenza vaccine, many healthcare institutions implemented mandatory COVID-19 vaccination polices.

Measures such as daily health questionnaires, temperature checks and weekly testing were insufficient in leu of vaccination. Non-medical exemptions to COVID-19 vaccine requirements increased the risk of COVID-19 to patients and healthcare workers. Healthcare facilities had a responsibility to protect the safety of patients and staff by evaluating exemption requests. It was very reasonable and consistent with available science to make a distinction between staff who interacted with more vulnerable versus less vulnerable patients for the purpose of evaluating exemption requests.

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CURRICULUM VITAE

Daniel Salmon

Home
168 Country Ridge Road
Red Lion, PA, 17356

Business
615 N. Wolfe Street, W5035
Baltimore, MD 21205
Tel: (443) 803-7754
E-mail: dsalmon1@jhu.edu

Global Disease Epidemiology and Control
Department of International Health
Department of Health, Behavior & Society
Institute for Vaccine Safety
The Johns Hopkins University
Bloomberg School of Public Health

Education and Training

2003 PhD, Health Policy and Management, Johns Hopkins University Bloomberg School of Public Health, Baltimore, MD
Dissertation: *School Implementation of Immunization Requirements: Are School Policies or Personnel Associated with the Likelihood of a Child Claiming an Exemptions or School-Based Outbreaks of Measles or Pertussis?*

1996 MPH, Health Policy and Management, Emory University Rollins School of Public Health, Atlanta, GA
Thesis: *Health Consequences of Religious and Philosophical Exemptions from Immunization Laws: Individual and Societal Risk of Measles*

1991 BA, Political Science with Minor in Psychology, Rutgers University, New Brunswick, NJ

Professional Experience

2018 - Director, Institute for Vaccine Safety, The Johns Hopkins University, Bloomberg School of Public Health

2017 - Professor, Global Disease Epidemiology and Control, Department of International Health, The Johns Hopkins University, Bloomberg School of Public Health

2017 - Professor, Health, Behavior and Society (joint appointment), The Johns Hopkins University, Bloomberg School of Public Health

2018 - 2021 Director of PhD Program, Global Disease Epidemiology and Control, Department of International Health, The Johns Hopkins University, Bloomberg School of Public Health

2012 - 2018	Deputy Director, Institute for Vaccine Safety, The Johns Hopkins University, Bloomberg School of Public Health
2012 - 2017	Associate Professor, Global Disease Epidemiology and Control, Department of International Health, The Johns Hopkins University, Bloomberg School of Public Health
2013 - 2017	Associate Professor, Health, Behavior and Society (joint appointment), The Johns Hopkins University, Bloomberg School of Public Health
2007 - 2012	Director of Vaccine Safety (GS 15 – Step 10), National Vaccine Program Office, Office of the Assistant Secretary for Health, Department of Health and Human Services
2007 - 2012	Adjunct Associate Professor, Global Disease Epidemiology and Control, Department of International Health, The Johns Hopkins University, Bloomberg School of Public Health
2005 - 2007	Associate Professor, Department of Epidemiology and Health Policy Research, University of Florida, College of Medicine
2003 - 2005	Assistant Scientist, Division of Disease Prevention and Control, Department of International Health, Associate Director for Policy and Behavioral Research, Institute for Vaccine Safety, The Johns Hopkins University, Bloomberg School of Public Health
2001 - 2003	Research Associate, Division of Disease Prevention and Control, Department of International Health, Associate Director for Policy and Behavioral Research, Institute for Vaccine Safety, The Johns Hopkins University, Bloomberg School of Public Health
1999 - 2001	Consultant, Institute for Vaccine Safety, The Johns Hopkins University, Bloomberg School of Public Health
2000	Consultant, Merck Vaccine Division, Merck and Co, Inc.
1997 - 1999	Policy Analyst, National Vaccine Program Office, Centers for Disease Control and Prevention
1995 -1997	Contractor, National Immunization Program, Centers for Disease Control and Prevention
1994 - 1995	HIV Prevention Community Coordinator, Health Visions, Inc.
1994	Consultant, Health Visions, Inc.

1990 - 1992 Residential Aide/Counselor, Alternatives, Inc.

Professional Activities

Society Membership

- American Public Health Association, Member (1995-1999)
- Infectious Disease Society of America, Member (2005-2007)

Advisory Panels

Advisory Panels

- National Academy of Science, Engineering, and Medicine. Guidance on Routine Childhood Immunization (2004)
- National Vaccine Advisory Committee (NVAC) Vaccine Confidence Working Group (2020-2022)
- Moderna Vaccine Safety Board (2020-2022)
- Merck Vaccine Confidence Board (2019, 2023)
- 39th National Immunization Conference External Planning Committee (2004)
- Merck Vaccine Policy Board Member (2007)
- Parents of Kids with Infectious Diseases (PKIDS), Board Member (2007- 2010)
- Brighton Collaboration, Board Member, Vaccine Hesitancy Working Group Co-Chair (2012-2020)
- National Vaccine Advisory Committee (NVAC) Vaccine Confidence Working Group (2018-22)
- Janssen Vaccine Policy Board Member (2021)
- Moderna Vaccine Safety Board (2022-2023)

Editorial Activities

Peer Reviewer (selected)

- American Journal of Preventive Medicine
- American Journal of Public Health
- Archives of Pediatric and Adolescent Medicine
- Biosecurity and Bioterrorism
- BMC Family Practice
- BMC Public Health
- Expert Reviews of Vaccines
- Health Affairs
- Health Education Research
- Indian Journal of Medical Science
- Journal of Comparative Family Studies
- Journal of Health Communication
- Journal of the American Medical Association
- Journal of the National Medical Association
- Journal of Urban Health

- New England Journal of Medicine
- Pediatrics Pediatric Infectious Disease Journal
- Pediatrics International
- Public Health Reports
- The Lancet
- The Lancet Infectious Diseases
- Vaccine
- Vaccines

Editorial Board
Vaccine, Associate Editor (2021- 2022)
Vaccines (2012-2013)

Guest Editor
Pediatrics Supplement: Vaccine Safety Throughout the Product Life Cycle (2011)
Vaccines Supplement: Confidence in Vaccines (2013)

Review of Proposals (selected)

Health Promotion in Communities (HPC) Study Section National Institutes of Health (standing member) and Dissemination & Implementation in Heath Study Section (DIHR, ad hoc reviewer). Special Emphasis Panels for National Institutes of Health, Centers for Disease Control and Prevention, Food and Drug Administration (Chair), National Science Foundation, and Canadian Institutes of Health Research.

Honors and Awards

- Haddon Fellow, Johns Hopkins University Bloomberg School of Public Health (1999-2001)
- Achievement Award – Dedication to Students, Johns Hopkins Bloomberg School of Public Health (2005)
- Development of the Federal Immunization Safety Task Force, Assistant Secretary for Health (2008)
- Federal Monitoring of H1N1 Vaccine Safety, Assistant Secretary for Health (2010)
- Patient Education Working Group Co-Chair, Assistant Secretary for Health (2012)
- Outstanding recent graduate (within past 10 years), Johns Hopkins Bloomberg School of Public Health (2013)
- Delta Omega Society (2014)

Publications **(* indicated student/advisee/mentee)**

Journal Articles (Peer Reviewed)

1. Powell TW, Forr A, Johnson S, Clinton T, Gaither J, Brewer J, Dudley MZ, Holifield J, Wilson P, Benson LR, Harr L, **Salmon DA**, Mendelson T. The Voices on Vax Campaign:

Lessons Learned from Engaging Youth to Promote COVID Vaccination. Prog Community Health Partnersh. 2024;18(3):345-353.

2. Kitano T, Dudley MZ, Engineer L, Thompson DA, **Salmon DA**. The authors reply to Kurita et al and Lataster. Am J Epidemiol. 2024 Jun 3;193(6):932-934.
3. Salmon DA, Orenstein WA, Plotkin SA, Chen RT. Funding Postauthorization Vaccine-Safety Science. N Engl J Med. 2024 Jul 11;391(2):102-105. doi: 10.1056/NEJMp2402379. Epub 2024 Jul 6.
4. Zapf AJ, Schuh HB, Dudley MZ, Rimal RN, Harvey SA, Shaw J, Balgobin K, **Salmon DA**. Knowledge, attitudes, and intentions regarding COVID-19 vaccination in the general population and the effect of different framing messages for a brief video on intentions to get vaccinated among unvaccinated individuals in the United States during July 2021. Patient Educ Couns. 2024 Jul;124:108258.
5. Dudley MZ, Schuh HB, Forr A, Shaw J, **Salmon DA**. Changes in vaccine attitudes and recommendations among US Healthcare Personnel during the COVID-19 pandemic. NPJ Vaccines. 2024 Feb 28;9(1):49.
6. **Salmon DA**, Chen RT, Black S, Sharfstein J. Lessons learned from COVID-19, H1N1, and routine vaccine pharmacovigilance in the United States: a path to a more robust vaccine safety program. Expert Opin Drug Saf. 2024 Feb;23(2):161-175.
7. Kitano T, **Salmon DA**, Dudley MZ, Thompson DA, Engineer L. Benefit-Risk Assessment of mRNA COVID-19 Vaccines in Children Aged 6 Months to 4 Years in the Omicron Era. J Pediatric Infect Dis Soc. 2024 Feb 26;13(2):129-135.
8. Dudley MZ, Schuh HB, Goryn M, Shaw J, **Salmon DA**. Attitudes toward COVID-19 and Other Vaccines: Comparing Parents to Other Adults, September 2022. Vaccines (Basel). 2023 Nov 21;11(12):1735.
9. Dudley MZ, Schwartz B, Brewer J, Kan L, Bernier R, Gerber JE, Budigan Ni H*, Proveaux TM, Rimal RN, **Salmon DA**. COVID-19 vaccination attitudes, values, intentions: US parents for their children, September 2021. Vaccine. 2023 Nov 30;41(49):7395-7408.
10. Delamater PL, Buttenheim AM, **Salmon DA**, Schwartz JL, Omer SB. Kindergarten Vaccination Status in California After Changes to Medical Exemption Policy. JAMA. 2023 Oct 24;330(16):1585-1587.
11. Schuh HB, Rimal RN, Breiman RF, Orton PZ, Dudley MZ, Kao LS, Sargent RH, Laurie S, Weakland LF, Lavery JV, Orenstein WA, Brewer J, Jamison AM*, Shaw J, Josiah Willock R, Gust DA, **Salmon DA**. Evaluation of online videos to engage viewers and support decision-making for COVID-19 vaccination: how narratives and race/ethnicity enhance viewer experiences. Front Public Health. 2023 Aug 21;11:1192676.
12. Kitano T*, Thompson DA, Engineer L, Dudley MZ, **Salmon DA**. Risk and Benefit of mRNA COVID-19 Vaccines for the Omicron Variant by Age, Sex, and Presence of Comorbidity: A Quality-Adjusted Life Years Analysis. Am J Epidemiol. 2023 Jul 7;192(7):1137-1147.
13. **Salmon DA**, Dudley MZ, Brewer J, Shaw J, Schuh HB, Proveaux TM, Jamison AM*, Forr A, Goryn M, Breiman RF, Orenstein WA, Kao LS, Josiah Willcock R, Cantu M, Decea T, Mowson R, Tsubata K, Bucci LM, Lawler J, Watkins JD, Moore JW, Fugett JH, Fugal A, Tovar Y, Gay M, Cary AM, Vann I, Smith LB, Kan L, Mankel M, Beekun S, Smith V, Adams SD, Harvey SA, Orton PZ. LetsTalkShots: personalized vaccine risk communication. Front Public Health. 2023 Jun 30;11:1195751.

14. Dudley MZ, Schuh HB, Shaw J, **Salmon DA**. Attitudes and Values of US Adults Not Yet Up-to-Date on COVID-19 Vaccines in September 2022. J Clin Med. 2023 Jun 8;12(12):3932.
15. Carleton BC, **Salmon DA**, Wong ICK, Lai FTT. Benefits v. risks of COVID-19 vaccination: an examination of vaccination policy impact on the occurrence of myocarditis and pericarditis. Lancet Reg Health West Pac. 2023 May 19;37:100797.
16. Schwartz B, Brewer J, Budigan H, Bernier R, Dudley MZ, Kan L, Proveaux TM, Roberts R, Tafoya N, Hamlin MD, Moore L, Hughes M, Turner B, Al-Dahir S, Velasco E, Privor-Dumm L, Veloz W, White JA, Dubois S, Ooton J, Kipp BJ, Show TJ, Salu K, Chavez B, Montes MDP, Najera R, King T, **Salmon DA**. Factors Affecting SARS-CoV-2 Vaccination Intent and Decision Making Among African American, Native American, and Hispanic Participants in a Qualitative Study. Public Health Rep. 2023 May-Jun;138(3):422-427.
17. **Salmon DA**, Plotkin S, Navar AM. Vaccine Decision-making in a Time of Conflicting Recommendations: A Call to Go Beyond Politics. Pediatr Infect Dis J. 2023 May 1;42(5):e138-e139.
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Commentaries

1. **Salmon DA**, Black S, Didierlaurent AM, Moulton LH. Commentary on "Common Vaccines and the Risk of Dementia: A Population-Based Cohort Study": Science Can be Messy but Eventually Leads to Truths. J Infect Dis. 2023 May 29;227(11):1224-1226.
2. Gostin LO, Shaw J, **Salmon DA.** Mandatory SARS-CoV-2 Vaccinations in K-12 Schools, Colleges/Universities, and Businesses. JAMA. 2021 Jun 7. *Invited*
3. Gostin LO, **Salmon DA**, Larson HJ. Mandating COVID-19 Vaccines. JAMA. 2021 Feb 9;325(6):532-533. doi: 10.1001/jama.2020.26553. PMID: 33372955. *Invited*
4. Opel DJ, **Salmon DA**, Marcuse EK. Building Trust to Achieve Confidence in COVID-19 Vaccines. JAMA Netw Open. 2020 Oct 1;3(10):e2025672. doi: *Invited*
5. **Salmon DA**, Dudley MZ, Carleton BC. Guillain-Barré Syndrome Following Influenza Vaccines Affords Opportunity to Improve Vaccine Confidence. J Infect Dis. 2021 Feb 13;223(3):355-358. doi: 10.1093/infdis/jiaa544. PMID: 33137189. *Invited*
6. **Salmon DA**, Dudley MZ. It is time to get serious about vaccine confidence. Lancet. 2020 Sep 26;396(10255):870-871. doi: 10.1016/S0140-6736(20)31603-2. Epub 2020 Sep 10. PMID: 32919522. *Invited*
7. Gostin LO, **Salmon DA**. The Dual Epidemics of COVID-19 and Influenza: Vaccine Acceptance, Coverage, and Mandates. JAMA. 2020 Jul 28;324(4):335-336. doi: 10.1001/jama.2020.10802. PMID: 32525519. *Invited*
8. **Salmon DA**, MacIntyre CR, Omer SB. Making mandatory vaccination truly compulsory: well intentioned but ill conceived. Lancet Infect Dis. 2015 Aug;15(8):872-3.
9. Halsey NA, **Salmon DA**. Measles at Disneyland, a problem for all ages. Ann Intern Med. 2015 May 5;162(9):655-6. *Invited*
10. Atwell JE*, **Salmon DA**. Pertussis resurgence and vaccine uptake: implications for reducing vaccine hesitancy. Pediatrics. 2014 Sep; 134(3): 602-4. *Invited*
11. **Salmon DA**, Halsey. Guillain-Barré Syndrome and vaccination. Clin Infect Dis. 2013 Jul; 57(2):205-7. *Invited*

12. **Salmon DA**, Halsey NA. Keeping the M in medical exemptions: protecting our most vulnerable children. J Infect Dis. 2012 Oct 1; 206(7): 987-8.
13. MacIntyre CR, Kelly H, Jolley D, Butzkueven H, **Salmon D**, Halsey N, Moulton LH Recombinant hepatitis B vaccine and the risk of multiple sclerosis: a prospective study. Neurology. 2005 Apr 12;64(7):1317.

Books

The Clinician's Vaccine Safety Resource Guide: Optimizing the Prevention of Vaccine-Preventable Diseases Across the Lifespan. Mathew Z. Dudley. **Daniel A Salmon**, Neal A. Halsey, alter A. Orenstein, Rupali J. Limaye, Sean T. O'Leary, Saad B. Omer. Springer Publishing, 2018.

Government and Advisory Committee Reports

1. White Paper on the United States Vaccine Safety System. National Vaccine Advisory Committee (NVAC), 2012. Role: Served as the Designated Federal Official for the Vaccine Safety Working Group with responsibilities including determining the charge and membership of the working group, holding closed and public meetings to gather scientific and programmatic information and incorporation of stakeholder views, and oversaw drafting of final report.
2. H1N1 Vaccine Safety Risk Assessment Working Group (VSRAWG). National Vaccine Advisory Committee (NVAC). Interim reports (12/2009, 1/2010, 2/2010, 3/2010, 4/2010, 6/2010) and final report (1/2012). Role: Served as the Designated Federal Official with responsibilities including determining the charge and membership of the VSRAWG, coordinating bi-monthly conference calls with the Federal Immunization Safety Task Force and the VSRAWG reviewing all H1N1 safety data, facilitated discussions of safety issues among the VSRAWG, drafting all reports.
3. Recommendations on 2009 H1N1 Influenza Vaccine Safety Monitoring. National Vaccine Advisory Committee (NVAC). 7/2009. Role: Served as the Designated Federal Official for the Vaccine Safety Working Group with responsibilities including determining the charge and membership of the Working Group, holding meetings with Working Group and HHS leadership, and drafting final report.
4. Federal Plans to Monitor Immunization Safety for Pandemic 2009 H1N1 Influenza Vaccination Program. Department of Health and Human Services, 2009. Role: Primary author with the Federal Immunization Safety Task Force.
5. Recommendations on the Centers for Disease Control and Prevention Immunization Safety Office Draft 5-Year Scientific Agenda. National Vaccine Advisory Committee (NVAC), 2009. Role: Served as the Designated Federal Official for the Vaccine Safety Working Group with responsibilities including determining the charge and membership of the working group, holding closed and public meetings to gather scientific and programmatic information and incorporation of stakeholder views, and oversaw drafting final report.
6. A Comprehensive Review of Federal Vaccine Safety Programs and Pubic Health Activities. Department of Health and Human Services, 2008. Role: Primary author with the Federal Immunization Safety Task Force.
7. Vaccine Safety Action Plan (Implementation Plan for the Task Force Report on Safer Childhood Vaccines). Department of Health and Human Services, 1999. Role: Primary author with the many HHS agencies (NIH, FDA, CDC, HRSA).

Practice Activities

Dr. Salmon's public health practice has been carried out while he held positions in the Federal government and academia and has resulted in 15 peer reviewed publications, 7 Federal and advisory committee reports, dozens of testimony to Federal advisory committees and state legislators, regular consultation with policy-makers, and more than 50 interviews with national media outlets. This practice work has been funded by state and Federal government agencies, has been integrated into Dr. Salmon's teaching, and has resulted in several awards for outstanding services by the Assistant Secretary for Health. Dr. Salmon's leadership has impacted policy and public health practice nationally. Dr. Salmon has assisted in the development of model state laws for school immunization requirements, based upon public health scholarship, and evaluated the impact of the application of this model. Dr. Salmon was a major contributor to realigning vaccine safety activities within the Centers for Disease Control and Prevention in order to provide greater public confidence in vaccine safety, surveillance and response activities.

While serving as the Director of Vaccine Safety at the National Vaccine Program Office, Dr. Salmon led an inter-agency and inter-departmental Secretarial task force, The Federal Immunization Safety Task Force, responsible for ensuring the coordination and strategic planning of Federal vaccine safety activities. Under his leadership, this Task Force wrote a Secretarial report to enhance our vaccine safety systems and the safety chapter of the National Vaccine Plan. Dr. Salmon led the development of the National Vaccine Advisory Committee (NVAC) Vaccine Safety Working Group, issuing reports to the Assistant Secretary for Health to improve the national vaccine safety system and focus vaccine safety research activities. This Working Group was cited by RAND on how to effectively utilize the National Vaccine Advisory Committee. The Department of Health and Human Services has been able to garner and focus vaccine safety programmatic and research activities through these internal government and advisory committee reports.

The 2009-10 H1N1 vaccine program brought unusual challenges and opportunities for vaccine safety and Dr. Salmon's work. The last national effort to quickly vaccinate the country to prevent a novel swine flu pandemic in 1976 resulted in a public health and political failure as the vaccine caused Guillain-Barré syndrome (GBS) and the pandemic never materialized as anticipated. The New York Times referred to this as the Swine Flu Fiasco as the Director of the Centers for Disease Control and Prevention and the Surgeon General were dismissed as President Ford faced public criticism. A new administration and the public remembered this experience as the 2009-10 H1N1 vaccine program was launched with considerable skepticism. Dr. Salmon seized these challenges and was able to capitalize on them to ensure the safety monitoring was robust and credible and build long lasting infrastructure.

Dr. Salmon oversaw the largest and most comprehensive vaccine safety monitoring program (2009-10 H1N1 vaccine program) ever in the US or internationally. Dr. Salmon worked with seven agencies in the Department of Health and Human Services, as well as the Departments of Defense and Veterans Affairs, to enhance active safety monitoring programs. Dr. Salmon developed a novel vaccine safety surveillance system, the Post Licensure Rapid Immunization Safety Monitoring (PRISM) Network that is now a part of permanent infrastructure at the Food

and Drug Administration and has served as a model for drug and product safety monitoring. Dr. Salmon led the Federal Immunization Safety Task Force to develop a safety-monitoring plan for H1N1 that was shared with stakeholders and the public and once the program was launched. To enhance public and stakeholder engagement and improve public confidence, Dr. Salmon developed the H1N1 Vaccine Safety Risk Assessment Working Group of the National Vaccine Advisory Committee that provided independent oversight of all 2009-10 H1N1 vaccine data across the government every two weeks and provided publically deliberated reports on a monthly basis throughout the vaccine program. Dr. Salmon's work in this area was cited by an Institute of Medicine report reviewing the National Vaccine Plan and Federal vaccine activities as an area in vaccines with exemplary leadership and coordination. Many aspects of this 2009-10 H1N1 vaccine program that were instituted under his leadership continue today.

Testimony

Dr. Salmon has made dozens of presentations to the National Vaccine Advisory Committee (NVAC), Advisory Commission on Childhood Vaccines (ACCV), the Advisory Committee on Immunization Practices (ACIP), and the National Biodefense Science Board (NBSB). He has also provided testimony for the Maryland and Florida Legislators.

Expert Testimony in Legal Cases (past 5 years)

1. *Mitra v Mullenax,*
   Court of Common Pleas, Crawford County, PA, Case No. F.D. 2022-35
   Testimony at trial

2. *Connolly v. Biomarin Pharmaceuticals Inc.*.
   USDC, Southern District of Texas, Case No. 4:23-cv-00938
   Testimony at arbitration hearing

3. *Marcoux, et al v. Eisenhower Medical Center*
   Riverside County, CA Superior Court, Case No. CVPS2203384
   Deposition

Presentations to Policy-Makers

Dr. Salmon has provided dozens of briefings for 3 CDC Directors, 3 Secretary's, two Deputy Secretary's, and 5 Assistant Secretary's for Health, U.S Department of Health and Human Services.

Consultations with Policy-Makers and Other Stakeholders

Served as the Federal Ex-Officio for the Advisory Commission on Childhood Vaccines (ACCV; 2007-2012) which provides advice to the Secretary, HHS, regarding the Vaccine Injury Compensation Program (HRSA). Developed working groups (as the Designated Federal Official) of the National Vaccine Advisory Committee (NVAC) that provides policy advice to the Director of the National Vaccine Program/Assistant Secretary for Health to optimize the prevention of disease through vaccination and the prevention of vaccine adverse events.

Through Dr. Salmon's leadership, the NVAC produced the following reports: 1) Review and prioritization of CDC Immunization Safety Office research agenda; 2) Recommendations for improving the Nations vaccine safety system; 3) Recommendations for improvements to H1N1 safety monitoring programs; and 4) Independent ongoing review of all H1N1 safety data. Through these Federal Advisory Committee efforts, Dr. Salmon worked closely with a very broad range of stakeholders including state and local health departments, Federal agencies (NIH, FDA, CDC, HRSA, IHS) and departments (HHS, DoD, VA, USAID), vaccine manufacturers, professional associations, academia, and advocacy organizations. Dr. Salmon has held many local, regional and national meetings to engage these stakeholders in vaccine policy and practice, issuing meeting reports, and impacting the policy and practice recommendation of the aforementioned advisory committee reports.

Research Finding Dissemination through Media Appearances

Dr. Salmon has made many media appearances and contributed to stories for CNN, Reuters News, The Associated Press, The New York Times, The Wall Street Journal, The Washington Post, The LA Times, and many other city, state and national media outlets.

Software Development

Developing and evaluating immunization App to increase maternal and infant vaccination uptake.

Practice Positions (outside academia)

Director of Vaccine Safety, National Vaccine Program Office, Office of the Assistant Secretary for Health, US Department of Health and Human Services (2007-2012): Coordinated, evaluated and provided leadership for federal vaccine safety programs.

- Developed a Secretarial Task Force (Federal Immunization Safety Task Force) issuing a report to the Secretary to enhance safety systems and providing ongoing coordination and leadership of Federal vaccine safety activities.
- Coordinated Federal H1N1 vaccine safety monitoring across multiple HHS Agencies and Departments, including development of federal strategic planning, addressing emerging issues, and development of innovative initiatives.
- Developed a novel active surveillance system (Post Licensure Rapid Immunization Safety Monitoring (PRISM)) for H1N1 vaccination program, capturing vaccine histories from 8 state immunization registries linked with health records for about 35 million persons through 5 large health insurance companies. This program is now a permanent part of vaccine safety monitoring by the FDA.
- Conducted a meta-analysis combining GBS data across multiple safety monitoring systems and worked with Vaccine Injury Compensation Program (HRSA) to determine if GBS should be a compensatable injury.
- Guest Edited supplement for Pediatrics to improve understanding of vaccine safety systems and science and enable effective communications by pediatricians when discussing vaccine safety with parents.

CURRICULUM VITAE

Daniel Salmon
Part II

Teaching

Masters Advisees

- Ann Marie Navar, 2005
- Jana Goins, 2005
- Bernadette Cambell, 2005
- Brian Rosen, 2013
- Kevin Wright, 2013
- Benjamin Williams, 2013
- Matthew Dudley, 2013
- Bansari Patel, 2013
- Oladeji Oloko, 2014
- Hannah Steinberg, 2014
- Moar Sherbini, 2014
- Aderemi Sanusi, 2016
- Caroline Picher, 2016
- Nicholas Albaugh, 2019
- Alex Zapf, 2020
- Emily Clifford, 2021
- Alexandria Cull Weatherer, 2021
- Alex Paulenich, 2022
- Azim Abdul Wahid, 2023
- Amar Fadeel, 2023
- Ana Stevens, 2024
- Gabby Liu (23/25 cohort)
- Angela Zhai (24/26 cohort)

Doctoral Advisees

- Dustin Gibson, PhD, 2014
- Matthew Dudley, PhD, 2019
- Andrea Carcelen, PhD, 2020
- Jennifer Gerber, PhD, 2020
- Taylor Halroyd, PhD, 2020

Preliminary Oral Participation

- Saad Omer, 2004
- Dustin Gibson, 2012

- Elizabeth Chmielewski, 2016

Final Oral Participation

- Saad Omer, 2006: "Societal Risk of Pertussis in the United States: Role of State Policies and Spatial Clustering of Childhood Vaccine Refusers"
- Ann Marie Navar, 2009: "Impact of Immunization in the Neonatal Intensive Care Unit"
- Zunera Gilani (alternate), 2012: "Population Immunity to Measles and Rubella Virus in Rural Zambia"
- Noor Rakshani, DRPH, 2013: "Individual and Contextual Level Factors Influencing Initiation, Completion and Up to Date Vaccination in Routine Immunization Program"
- Jennifer Kreslake (chair), 2014: "Determinants of Risk Behaviors in the Containment of Highly Pathogenic Avian Influenza and Implications for Risk Communication"
- Dustin Gibson, 2014: "The Readiness, Need for, and Effect of mHealth Interventions to Improve Immunization Timeliness and Coverage in Rural Western Kenya"
- Brittany Kmush, 2016: "Determinants of Immunologic Persistence of Hepatitis E Virus Antibodies." (alternate)

MSPH/Post-MPH Internships Hired and Supervised (Current position, number of co-authored papers)

- Ann Marie Navar, 2006 (Associate Professor of Medicine (Cardiology)
- UT Southwestern Medical School; 5 papers)
- Terrel Carter, 2007 (American Academy of Pediatrics, Global Immunization Staff; 4 papers)
- Stephanie Irving, 2007 (Kaiser Permanente Center for Health Research; 1 paper)
- Kirsten Vannice, 2008-10 (World Health Organization & Gates; 6 papers)
- Michelle Mergler, 2009-10 (Johns Hopkins Doctoral Student; 2 papers)
- Will Bleser, 2010 (Duke Policy Center; 3 paper)

Classroom Instruction

Primary Instructor

2003 - Vaccine Policy Issues (223.687.01). This 3-credit course examines current national and international policy issues in vaccine research, development, manufacturing, supply, and utilization. Topics include development of orphan vaccines, ensuring an adequate supply of safe and effective vaccines, vaccine injury compensation, and disease eradication. Emphasizes the identification of important vaccine policy issues and the development and evaluation of policies to address these issues. Presents the roles, responsibilities, and policy positions of key immunization stakeholders via guest lectures by a wide array of experts who have worked for important vaccine groups (i.e., FDA, GAVI, Vaccine Industry, US Vaccine Injury Compensation Program, Consumer Group). 35-45 students masters and doctoral students from across the School of Public Health and

Preventive Medicine Residents. Consistently received high student course evaluations.

2018 - The Practice of Public Health Through Vaccine Case Studies: Problem Solving Seminar (223.630.81). Vaccines are among the most effective medical and public health interventions. This class for DrPH students presents historic vaccine case studies highlighting challenges in emerging science, program design and evaluation, management, policy and communication. The seminar examines decision-making surrounded by scientific uncertainty, controversy and competing public health priorities and explores the challenges of developing policy and practice decisions within the constraints of emerging and uncertain science. Students are challenged to make policy decisions and develop programmatic and communication strategies in real world settings.

2012 - 2013 Vaccine Policy Issues (223.687.98). Johns Hopkins Fall Institute, Barcelona, Spain.

Co-Instructor

2004-05 Public Health Practice (305.607.01). This 4 credit course focused on the areas of knowledge and skills necessary to the administration of health agencies. The course covered topics such as administrative structure, intergovernmental relations, legislation, politics, and the public budgetary process with reference to health departments on the federal, state, and local levels. The course also reviewed public sector issues for which health agencies are responsible, including AIDS, health promotion strategies, primary care, and immunization programs. Developed and taught class on-site and online.

Research Grant Participation

Adult Immunization Quality Improvement for Providers (IQIP)
Sponsor: CDC
Role: Principal Investigator (15% effort)
Dates: 08/01/23 – 08/01/26
Project: Develop, evaluate and widely disseminate an evidence-based QI program for immunization that integrates adult-specific strategies across healthcare provider settings.

Evaluating Social Media as a Tool for Connecting Vulnerable Communities with a Personalized Vaccination Decision-Making Website
Sponsor: Vaccine Confidence Fund
Role: Principal Investigator (15% effort)
Dates: 04/01/23 – 03/01/24
Project: Evaluate the relative impact and cost effectiveness of grassroot public health efforts vs. paid social media strategies on community engagement with LetsTalkShots.

LetsTalkCOVIDVaccines | Orange County, New York
Sponsor: Orange County Health Department
Role: Principal Investigator (20% effort)

Dates: 12/01/22 – 12/01/23
Project: Pilot the LetsTalkShots provider talking points with Little Pediatrics in Orange County, NY.

Improving Vaccine Acceptance through EHR Integrated Patient- and Provider-Facing Decision Support
Sponsor: Merck Sharp And Dohme Corp
Role: Principal Investigator (10% effort)
Dates: 11/01/22 – 11/01/24,
Project: Establish the technical feasibility and evaluate the effectiveness of a scalable, integrated platform to improve patient informed decision-making and increase vaccine uptake.

Health Care Provider Training to Increase Vaccine Uptake and Reduce Vaccine Hesitancy
Sponsor: Merck Sharp And Dohme Corp
Role: Principal Investigator (15% effort)
Dates: 01/11/2021 – 01/10/2025
Project: Develop and evaluate Johns Hopkins CME module teaching how clinicians can effectively communicate with patients about vaccines and conversion of Springer published clinical guide into Unbound Medicine version.

Public and Health Care Provider knowledge, attitudes, beliefs, intentions, and behaviors regarding COVID-19 disease and SARS-CoV-2 vaccines: the mediating role of trust in health care providers and public health authorities
Sponsor: Merck Sharp And Dohme Corp
Role: Principal Investigator (10% effort)
Dates: 01/11/2021 – 01/11/2024
Project: Evaluate the immediate impact of outbreaks of COVID-19 disease and response measures on uptake of recommended vaccines, including but not limited to SARS-CoV-2 vaccines (when such vaccines are recommended), with a focus on trust in health care providers and public health authorities, and their vaccine knowledge, attitudes
and beliefs.

TweenVax: A comprehensive practice-, provider-, and parent/patient-level intervention to improve adolescent HPV vaccination
Sponsoring Agency: National Cancer Institute, National Institutes of Health
Role: Co-Investigator (5% effort)
Dates: 09/01/2019 – 06/30/2024
Project: The aim of the project is to develop and refine the practice-, provider-, and patient/parent-level intervention that will be tested in primary care pediatric and family practice offices for adolescents aged 9-14.

LetsTalkCovidVaccine Tailored for Local Communities
Sponsor: NACCHO
Role: Principal Investigator (20% effort)
Dates: 12/1/2021 - 7/31/2023
Project: Tailored LetsTalkCovidVaccine, a personalized health communication tool, to five underserved communities.

Assessing Vaccine Hesitancy and a Pharmacist Led Intervention Model to
Sponsor: XULA
Role: Co- Investigator (5% effort)
Dates: 11/13/2020 - 5/23/2023
Project: Training pharmacists to work with vaccine hesitant patients.

LetsTalkCovidVaccine Tailored for Guilford County
Sponsor: GCGPH
Role: Principal Investigator (5% effort)
Dates: 3/1/2022 - 10/31/2022
Project: Tailored LetsTalkCovidVaccine, a personalized health communication tool, to Guildford County, NC.

CGHI Vaccine Access and Training (VAT) Initiative for a Community-Based Workforce
Sponsor: GHC3
Role: Co-Investigator (20% effort)
Dates: 3/1/2022 - 10/31/2022
Project: Trained over 100 community health workers to go into their vulnerable communities and work with vaccine hesitant persons.

Vaccine Hesitancy for COVID 19
Sponsor: NACHC
Role: Principal Investigator (20% effort)
Dates: 7/15/2021 - 6/30/2022
Project: Built LetsTalkCovidVacciens, a personalized risk communication tool, based on our MomsTalkShots model.

Let's talk COVID shots web app for Canadians
Sponsor: CPHA
Role: Principal Investigator (10% effort)
Dates: 10/1/2021 - 3/18/2022
Project: Tailored LetsTalkCovidVaccine, a personalized health communication tool, for Canada.

SARS-CoV2 Vaccines Information Equity and Demand Creation Project (COVIED)
Sponsor: Centers for Disease Control and Prevention
Role: Multiple Principal Investigator (mPIs Robert Breiman and Walter Orenstein) (25% effort)
Dates: 02/01/2021-09/31/2021
Project: Implements a systematic approach to provide interpretable, context- and culture-specific accurate and trusted information about the vaccines that will be offered, and to package and deliver this information to susceptible populations at risk for COVID and demonstrating vaccine hesitancy as a means to substantively reduce the disproportionate impact of COVID illness and death associated with this pandemic.

Understanding Diverse Communities and Supporting Equitable and Informed COVID-19 Vaccination Decision-Making
Sponsor: Robert Wood Johnson Foundation

Role: Principal Investigator (20% effort)
Dates: 11/1/2020-9/1/2021
Project: Collaborat with NACCH, ASTHO, AIM and NIHB to better understand how people are approaching decision-making regarding COVID-19 vaccination and what additional information they need to make an informed decision for themselves, their family, and their community.

Valuation of Vaccine Safety
Sponsor: GAVI
Role: Principal Investigator (20% effort)
Dates: 07/15/2020 – 07/31/2021
Project: Quantify the health and economic costs associated with the vaccine safety disaster that occurred in the Ukraine in 2008 where there was a decline in vaccine public confidence triggered by mishandled death following a measles vaccine campaign, leading to a large measles outbreak including exportation to other countries.

Impact of Eliminating Non-Medical Exemptions in California
Sponsoring Agency: National Institute of Allergy and Infectious Diseases, National Institutes of Health
Role: Co-Investigator (20% effort)
Dates: 2016-2021
Project: California is the first state in decades to abolish non-medical exemptions to school immunization requirements. This study examines the implementation and impact of this change by assessing the burdens on health care providers, health departments, schools and parents and the rates of medical exemptions and home schooling.

PHASE II: Development and Writing of the Global Vaccine Safety Blueprint 2.0
Sponsor: WHO
Role: Principal Investigator (15% effort)
Dates: 1/17/2020 - 4/30/2020
Project: In collaboration with the World Health Organization, drafted verson 2.0 of the Global Vaccine Safey Blueprint.

Ethical, Legal and Social Issues (ELSI) for Precision Medicine and Infectious Disease: Centers for Excellence in ELSI Research (CEER)
Sponsoring Agency: National Human Genome Research Institute, National Institutes of Health
Role: Co-Investigator, Lead Vaccinomics (15% effort)
Dates: 2016-2020
Project: Anticipate and examine the ethical, legal, social, historical and policy issues confronting the incorporation of genomics in the prevention, outbreak control, and treatment of a range of infectious diseases, and plan for the responsible translation of genomic advances into practice.

A Comprehensive Pre-natal Intervention to Increase Vaccine Coverage
Sponsoring Agency: National Institutes of Health: Dissemination and Implementation Research in Health (R01)
Role: Multiple Principal Investigator (with Saad Omer, Emory University) (35% effort)
Dates: 2015-2020
Project: Develop and evaluate a comprehensive intervention at the patient, provider and practice

levels to increase maternal and childhood vaccine uptake.

Cocooning (influenza and Tdap vaccines)
Sponsor: Walgreens
Role: Principal Investigator (15% effort)
Dates: 1/26/2017 - 6/30/2019
Project: Randomized controlled Trial to ascertain the impact of MomsTalkShots on friends and family of pregnant women.

The Vaccine Safety Communication E-Library
Sponsor: WHO
Role: Principal Investigator (5% effort)
Dates: 02/01/2019 – 04/30/2019
Project: The objective is to work with the WHO vaccine safety office to develop the e-library by assisting with growing the content and enhancing the organization and searchability of the VSN e-library and the development of a plan of action to increase participation of members and new members.

Programmatic Impact of Multi-dose Vaccines
Sponsoring Agency: Bill and Melinda Gates Institute through the Johns Snow Institute
Role: Co-Investigator (10% effort)
Dates: 2016-2018
Project: Equip global and country level decision makers with the evidence, guidance, and tools needed to assess when, where, and how the selection of vaccine presentation affects timely, equitable, and safe vaccination coverage.

Case Studies of the Impact of Meningitis Epidemics on Local Health Departments and College Health Facilities
Sponsoring Agency: Pfizer
Role: Principal Investigator (25% effort)
Dates: 2015-2016
Project: Evaluate the non-medical costs associated with Meningitis outbreaks in university settings.

Capitalizing on Recent Changes to School Immunization Requirements to Improve the Publics Health
Sponsoring Agency: Robert Wood Johnson Foundation Public Health Law Program
Role: Hopkins Principal Investigator (10% effort)
Dates: 2014-2016
Project: Evaluate the implementation and impact of recent changes made to state school immunization requirements and develop model school immunization law.

Note: Dr. Salmon was a Federal employee for 5 years and consequently could not receive external funding

Evaluation of Parents Claiming Exemptions to School Entry Immunization Requirements

Sponsoring Agency: Centers for Disease Control and Prevention
Role: Principal Investigator (20% effort)
Dates: 2004-2006
Project: Examine the secular trends and geographical clustering of immunization exemptions and associations with pertussis, reasons why parents refuse vaccines, and conducted a content analysis of vaccine safety newspaper stories.

Mentored Patient-Oriented Research Career Development Award (K23). Decision Making of Parents to Vaccinate Their Children
Sponsoring Agency: National Institutes of Health
Role: Principal Investigator (75% effort)
Dates: 2004-2007
Project: Explore the role of health care providers in influencing parental vaccination decisions.

Policy and Ethical Consultation on Pandemic Planning and Public Health Emergencies
Sponsoring Agency: Florida Department of Health
Role: Principal Investigator (10% effort)
Dates: 2005-2006
Project: Explore ethical issues regarding responding to an influenza pandemic and developed a training module for public health workers to understand ethical issues surrounding vaccination during a pandemic.

Implementation of Mandatory Immunization Requirements
Sponsoring Agency: Centers for Disease Control and Prevention
Role: Co-Principal Investigator (with Neal Halsey) (75% effort)
Dates: 2001-2003
Project: Assess the role of school personnel and school policies in implementing immunization requirements. Explored the reasons why some parents claim exemptions to school immunization requirements.

The Role of School Personnel and Policies in Implementing Immunization Requirements
Sponsoring Agency: Washington State Department of Health
Role: Principal Investigator (10% effort)
Dates: 2001-2004
Project: Explore the role of school personnel and school policies in implementing immunization requirements in Washington State.

Academic Service

2003 - 2005	Admissions Committee for MSPH Program, Disease Prevention and Control, Department of International Health, Johns Hopkins Bloomberg School of Public Health
2005 - 2007	Epidemiology Program Director, Interdisciplinary Program (IDP), University of Florida, College of Medicine
2012 -	Admissions Committee for PhD Program, Global Disease Epidemiology and Control, Department of International Health, Johns Hopkins Bloomberg School of Public Health

2014 - Honors and Awards Committee, Department of International Health, Johns Hopkins Bloomberg School of Public Health
2015 - Public Health Practice Committee, Johns Hopkins Bloomberg School of Health

Advisory Committee Presentations **(selected)**

2020 National Vaccine Advisory Committee, Vaccine Confidence Working Group
2006 National Vaccine Advisory Committee, Adolescent Vaccine Working Group. *History and Impact of School Immunization Requirements: Implications for Adolescent Vaccination*
2004 National Vaccine Advisory Committee, Subcommittee on Vaccine Safety. *Enhancing Public Confidence in Vaccines through Independent Oversight of Post-Licensure Vaccine Safety*
2002 National Vaccine Advisory Committee Working Group on Implementing Vaccine Recommendations, *presentation to the Committee and expert witness for panel discussion*
1998 National Vaccine Advisory Committee Working Group on Philosophical Exemptions, *presentation to the Committee*

Personal Statement

Dr. Salmon's primary research and practice interest is optimizing the prevention of childhood infectious diseases through the use of vaccines. He is broadly trained in vaccinology, with an emphasis in epidemiology, behavioral epidemiology, and health policy. Dr. Salmon's focus has been on determining the individual and community risks of vaccine refusal, understanding factors that impact vaccine acceptance, evaluating and improving state laws providing exemptions to school immunization requirements, developing systems and science in vaccine safety, and effective vaccine risk communication. Dr. Salmon has considerable experience developing surveillance systems, using surveillance data for epidemiological studies, and measuring immunization coverage through a variety of approaches. Dr. Salmon has worked with state and federal public health agencies to strengthen immunization programs and pandemic planning.

Controversies have always existed around vaccines. However, increasingly parents are worried about the safety of vaccines and the rates of parents refusing vaccines have been increasing. Dr. Salmon's led the first study quantifying the individual and community risks of measles associated with vaccine refusal. He and others have replicated these studies examining the risk of vaccine refusers for pertussis, *Haemophilus influenzae* type b, varicella, and pneumococcal. Dr. Salmon's studies in this area have demonstrated that local clustering of refusal is associated with measles and pertussis, explaining why we see sporadic measles outbreaks despite very high vaccine coverage nationally. Dr. Salmon's work quantifying the individual and community risks of disease resulting from vaccine refusal has directly impacted national and state policy in this area.

Having quantified the magnitude of the problem of vaccine refusal, Dr. Salmon conducted a broad range of studies examining factors that contribute to vaccine acceptance and refusal. He conducted studies comparing parents who refused vaccines for their children compared to parents of fully vaccinated children. He then linked these parents to their healthcare providers to understand the impact of healthcare providers on parental vaccine decision-making. Dr. Salmon conducted studies exploring the impact of school-level personnel and policies on vaccine refusal and the impact of the media's focus on vaccine safety.

Dr. Salmon's investigations of parents who refuse vaccines for their children have included parents who claim exemptions to school immunization requirements because they are actively deciding to refuse vaccines altogether rather than delay vaccines. Dr. Salmon has investigated compulsory vaccination in the US compared to other developed countries. He has explored how school laws are implemented and enforced at the state and local level and how this impacts the rates of exemptions. He developed an evidence-based model state exemption law that has been implemented in various forms in many states to strengthen their state exemption laws. He has evaluated the impact of these applications of this model and is in the process of revising this model law with a broad range of stakeholders. Dr. Salmon's work in this area has largely shaped the debate we see in many states making exemption laws more stringent and offers a policy approach to limiting exemptions while preserving parental autonomy.

Concerns about the safety of vaccines are the primary (but not the only) reason that parents are increasingly refusing vaccines. Dr. Salmon has focused on developing the science base for vaccine safety. He served as the Director for Vaccine Safety, National Vaccine Program Office, HHS, where he was responsible for coordinating and leading our national vaccine safety efforts

including, but not limited to, the 2009 H1N1 vaccine program. In this capacity, Dr. Salmon improved our vaccine safety systems. During the H1N1 vaccine program he oversaw the largest, most comprehensive vaccine safety monitoring program ever in the US and the world. Dr. Salmon developed a new active surveillance system (Post-licensure Rapid Immunization Safety Monitoring (PRISM) Network) that is now a permanent part of our vaccine safety monitoring program. He created independent vaccine safety assessment to improve trust and confidence. The success of these efforts was highlighted by the IOM when reviewing the National Vaccine Plan. Dr. Salmon has also conducted safety studies, such as the most comprehensive evaluation of GBS post-influenza vaccine since 1976. Dr. Salmon is currently a board member of the Brighton Collaboration, an international network of vaccine safety investigators, and co-chairs their vaccine confidence working group.

While improving safety systems and science is essential to addressing parental safety concerns, it is necessary to effectively communicate the risks and benefits of vaccines to the scientific community, healthcare providers, the media and the public. To work toward this objective, Dr. Salmon has conducted vaccine risk perception and communication studies, developed communication strategies for the Department of Health and Human Services and its Agencies, and developed resources for healthcare providers. Dr. Salmon is currently focused on developing and evaluating interventions at the patient, provider and practice levels to improve maternal and infant vaccine acceptance. Dr. Salmon was the guest editor to a supplement in Pediatrics that assisted pediatricians in working with vaccine hesitant parents by reviewing the complex vaccine safety system in the US, reviewing factors that impact vaccine hesitancy, and assisting pediatricians with how to communicate with parents. Dr. Salmon is widely considered a national and international expert in vaccine safety and factors impacting vaccine acceptance.

Keywords

Vaccine, Immunization, Infectious Diseases, Epidemiology, Health Policy, Public Health Practice

Exhibit F

Message

From: BHebel@dh.org [BHebel@dh.org]
Sent: 8/30/2021 8:39:16 PM
CC: AEdelson@dh.org
Subject: COVID-19 Vaccine Requirement Information

As frontline caregivers, our essential role in protecting the health and wellbeing of our communities goes beyond the care we provide. As a valued and trusted voice, our example is perhaps the strongest health resource we have. **Therefore, in keeping with our commitment to protect the health and safety of our Associates, volunteers, patients, Medical Staff and the community we proudly serve, Doylestown Health will require that all Associates, volunteers and Medical Staff members, whether or not they provide direct patient care, and whether they work on campus or remotely, be vaccinated against COVID-19.**

Our timeline for completing the vaccine series and meeting this requirement will be **October 4, 2021**. First dose vaccinations must be administered, no later than **September 10, 2021**; with the second dose being completed by **October 4, 2021**. We will follow Doylestown Health's current vaccination policy (which is attached.) In those instances when an individual is unable to get vaccinated due to a documented medical condition or significantly held religious belief, Doylestown Health will follow the established process for requesting an exemption consistent with our overall vaccination policy for other diseases including flu, hepatitis B, etc. To offer convenient access to the vaccine, we have been offering vaccine clinics at a variety of locations free of charge. The remaining clinic are scheduled to get your vaccine. Please schedule a time ASAP. If you are not able to attend one of the on-site vaccination clinics, you may choose to get vaccinated by another COVID-19 vaccination provider or site throughout the community. **Any Associate that has received the vaccination through an outside organization must provide proof of inoculation by October 4, 2020 to the Occupational Health Department.**

NOTE: If receiving the J& J vaccine, Associates may schedule anytime up until October 4, 2021

How to sign up for a vaccine appointment:

Please use the links below to sign up for a vaccine appointment. Due to recent upgrades, do not use Internet Explorer to sign up. You are unable to access dates/times.

Please **COPY + PASTE** the link of the date you want to sign up for into Google Chrome directly. Google Chrome is the red, yellow, and green icon.

LOCATION: HOSPITAL – Old rehab area off of the Main Lobby

Tuesday, 8/31 4pm-7:50pm - Pfizer and J&J Vaccine
https://www.eventbrite.com/e/166157147501

Friday, 9/3 5:30 am – 9 am – Moderna and J&J Vaccine
https://www.eventbrite.com/e/166155085333

Tuesday, 9/7 4pm-7:50pm - Pfizer and J&J Vaccine
https://www.eventbrite.com/e/166157699151
Additional clinics will be added for J&J - watch for e-mails.

URGENT CARE – Swamp Road – across from Thompson BMW

Wednesday, 9/1 - noon -4 pm - Pfizer and J&J Vaccine

https://www.eventbrite.com/e/166188266579

Wednesday, 9/8 - noon -4 pm - Pfizer and J&J Vaccine
https://www.eventbrite.com/e/166189109099

Should you have any questions or comments, we have established two communication lines:

Online Form- insert this link **https://doylestownhealth.formstack.com/forms/associate_covid_vaccine_questions**
Voicemail
215-489-1247 (x1247)

We are confident that together, we can make a different in the fight against this pandemic so that we can continue to grow and meet the needs of the community we serve who come to us for care.

Barbara A Hebel
Vice President and Chief Human Resources Officer
Doylestown Health System
595 West State Street
Doylestown, PA 18901
bhebel@dh.org
215-345-2688

Exhibit G

American Board of Internal Medicine®

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October 18, 2022 ABIM ID: 136084

Peter McCullough, M.D.
5231 Richard Avenue
Dallas, TX 75206

Personal and Confidential
Sent by Certified Mail

Re: Notice of Recommended Disciplinary Sanction

Dear Dr. McCullough:

The American Board of Internal Medicine (ABIM) provided you notice by letter dated May 26, 2022 (the "Notice") that ABIM's Credentials and Certification Committee (CCC) would consider whether to recommend a disciplinary sanction against you in light of public statements you made about the purported dangers of, or lack of justification for, COVID-19 vaccines.

The CCC met to consider this matter on July 26, 2022. Present for the meeting were Furman S. McDonald, M.D., M.P.H., Senior Vice President for Academic and Medical Affairs, and chair of the CCC; Richard Battaglia, M.D., FACP, Chief Medical Officer; Lorna Lynn, M.D., Vice President, Medical Education Research; Jeffrey Miller, Chief Information Officer; Michael Melfe, Director, Academic Affairs; Ruth Hafer, Credentials and Licensure Manager; Kathryn Ross, Ph.D., Research Associate; and Lauren Duhigg, Senior Research Associate. Also present were Paul Lantieri III and Emilia McKee Vassallo of Ballard Spahr LLP, counsel to ABIM.

Background

You are currently certified by ABIM in Internal Medicine and Cardiovascular Disease.

You have made numerous widely reported and disseminated public statements about the purported dangers of, or lack of justification for, COVID-19 vaccines. In March 10, 2021 testimony before the Texas Senate Committee on Health & Human Services, you stated, among other things, that there is no "scientific, clinical, or safety rationale for ever vaccinating a Covid-recovered patient," and that there is "no scientific rationale" for healthy people under 50 to receive a Covid vaccine. Testimony available at https://www.youtube.com/watch?v=QAHi3lX3oGM. Similarly, you asserted in a national television interview that "[t]here is no reason [people who have previously had COVID-19] should take the vaccine." Transcript of *Ingraham Angle*, Fox News Network, June 29, 2021.

You also have reportedly stated that as many as 50,000 Americans may have died due to Covid-19 vaccines in the first half of 2021. *See, e.g.*, D. Villareal, *7 Doctors at Anti-Vax Summit Catch COVID-19 Despite Touting Ivermectin "Treatment,"* Newsweek, Nov. 23, 2021; K. Krause, *System Sues Vaccine Skeptic*, Dallas Morning News, July 30, 2021; *Alarm Grows as Researchers Warn of Dangers of the COVID-19 Shots*, Mizzima, July 25, 2021. And in another public forum, you reportedly asserted that Covid-19 vaccines are part of "bioterrorism research." *Moscow COVID Delta Response May Shock Government Officials*, Newstex Blogs, The Duran, June 26, 2021.

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In addition, in a declaration submitted in support of the plaintiffs in *State of Louisiana, et al. v. Becerra*, No. 3:21-cv-03970-TAD-KDM (W.D. La.), on November 15, 2021 ("*Louisiana* Decl."), you declared – after noting your ABIM certification as part of your background (*Louisiana* Decl. ¶ 4) – that Covid-19 presents a "negligible risk for adults younger than the age of 60" (*Louisiana* Decl. ¶ 9); that "[b]ased on VAERS as of October 29, 2021, there were 18,078 COVID-19 vaccine deaths reported"; and that "COVID-19 mass vaccination is associated with at least a 39-fold increase in annualized vaccine deaths reported to VAERS" (*Louisiana* Decl. ¶ 29).

In response to the Notice, you submitted a letter dated June 14, 2022 "request[ing] prompt dismissal of the matter" or the "right to attend and personally participate and/or have legal counsel represent [you] in the ABIM Credentials and Certification Committee meeting." You included with your letter a "point-by-point declaration" responding to the Notice ("McCullough Decl."). In the McCullough Declaration, you state that you "have been a leader in the medical response to the COVID-19 disaster and have published or been listed on many publications and given testimony before various government bodies. (McCullough Decl. ¶ 5.) Among other things, you discuss and cite purported support for your views of the risks of COVID-19 vaccines (McCullough Decl. ¶ 11-33), and you make a number of statements that echo those you have previously made that are described above. For example, you state that "[t]here is negligible mortality risk [from COVID-19] for adults younger than the age of 50" and that "[t]here is no scientific rationale, medical necessity, or clinical indication for people under age 50 or 60 in general to receive a COVID-19 vaccine" (McCullough Decl. ¶ 8, and p. 18 (Conclusion ¶ 4)), and that "the COVID-19 mass vaccination is associated with at least a massive increase in deaths reported to [the Vaccine Adverse Event Reporting System (VAERS)]" (McCullough Decl. ¶ 23; *see also, e.g.*, McCullough Decl. ¶¶ 24-29 (discussing VAERS and other purported adverse event data in connection with COVID-19 vaccines).

In addition, ABIM received a letter concerning your disciplinary proceeding from United States Senator Ron Johnson, and a letter titled, "Open Letter to the American Board of Medical Specialties and the Federation of State Medical Boards: The destruction of Member Boards' credibility," dated June 26, 2022, with dozens of signatures, "condemn[ing]" the "decision to review" your board certification and others "on the frivolous grounds that they are spreading 'medical misinformation.'"

As set forth in the Notice, ABIM's "False or Inaccurate Medical Information" policy provides:

> While ABIM recognizes the importance of legitimate scientific debate, physicians have an ethical and professional responsibility to provide information that is factual, scientifically grounded, and consensus driven. Providing false or inaccurate information to patients or the public is unprofessional and unethical, and violates the trust that the profession of medicine and the public have in ABIM Board Certification. Therefore, such conduct constitutes grounds for disciplinary sanctions.

(*See* ABIM's Policies & Procedures for Certification (P&P), at p. 19. A printed copy of the P&P was provided with the Notice. The P&P is also available on ABIM's website at http://www.abim.org/about/publications/certification-guides.aspx.)

ABIM's "Disciplinary Sanction and Appeals" policy further provides that ABIM may impose disciplinary sanctions, including the suspension or revocation of board certification or

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participation in the certification or Maintenance of Certification processes, invalidation of an examination, or other professional sanctions, if ABIM obtains evidence that in its judgment demonstrates that a candidate or diplomate: (1) has had a license to practice medicine restricted in any jurisdiction, has surrendered a license but continues to hold a valid license in another jurisdiction, or has had one or more licenses suspended or revoked but continues to hold a valid license; (2) engaged in irregular or improper behavior or other misconduct in connection with an ABIM examination; (3) made a material misstatement of fact or omission in connection with ABIM with an application, or misrepresented their board certification or Board Eligibility status with anyone; (4) failed to maintain moral, ethical, or professional behavior satisfactory to ABIM; or (5) engaged in misconduct that adversely affects professional competence or integrity. (P&P at p. 18.)

Decision

As an initial matter, the CCC reviewed your request to participate or be represented by counsel at the meeting of the CCC. The CCC respectfully refers you to the Notice and the other information about ABIM's Disciplinary Sanction and Appeals process set forth in the P&P. The CCC considers documentary evidence and submissions, and physicians who wish to appeal CCC-recommended sanctions have the right of appeal with a hearing before a panel of physicians. (Notice at p. 3; P&P at p. 18; *see also* Appeal Rights, below.)

In its consideration of this matter, the CCC focused particularly on your statements asserting that the mortality risk of COVID-19 is "negligible" for people who are under the ages of 50 or 60, and that there is no medical reason for that population to receive COVID-19 vaccines. (*See* Background, above.) The CCC found that those statements are not factual, scientifically grounded, or consensus driven. Indeed, according to the CDC, from January 1, 2020 to October 8, 2022, more than 71,000 Americans under the age of 50 have died from COVID-19, representing nearly 8% of all deaths for that age group. Moreover, more than 194,000 Americans aged 50 to 64 have died from COVID-19, representing over 12% of all deaths in that age group during the same time period. *See* Centers for Disease Control and Prevention, COVID-19 deaths by sex, age, state, year, and months, https://data.cdc.gov/widgets/9bhg-hcku?mobile_redirect=true (updated as of Oct. 8, 2022).

The CCC also focused on your statements, purportedly relying on VAERS data, suggesting or otherwise insinuating that COVID-19 vaccines themselves have caused or been associated with tens of thousands of deaths that would not have occurred but for the vaccines. The CCC found that those statements are not supported by VAERS data or any other reliable source. Centers for Disease Control and Prevention, COVID-19, Reported Adverse Events, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html (updated Oct. 12, 2022) (reporting that "severe reactions after vaccination are rare," and that "[t]he benefits of COVID-19 vaccination continue to outweigh any potential risks"); World Health Organization, Safety of COVID-19 Vaccines, https://www.who.int/news-room/feature-stories/detail/safety-of-covid-19-vaccines (March 31, 2021) (stating that "[b]illions of people have been safely vaccinated against COVID-19," that "mRNA vaccines [for COVID-19] have been rigorously assessed for safety, and clinical trials have shown that they provide a long-lasting immune response," and that "mRNA vaccines are not live virus vaccines and do not interfere with human DNA"). Your suggestions otherwise misrepresent the facts reported in VAERS. Thus, those statements are likewise not factual, scientifically grounded, or consensus driven.

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Nothing in your declaration submitted in response to the Notice, or in the materials submitted to ABIM on your behalf, compels a different conclusion.

For these reasons, the CCC found that you have provided false or inaccurate medical information to the public. By casting doubt on the efficacy of COVID-19 vaccines with such seemingly authoritative statements, made in various official forums and widely reported in various media, your statements pose serious concerns for patient safety. Moreover, they are inimical to the ethics and professionalism standards for board certification.

In light of all the evidence and circumstances, the CCC determined to recommend that your board certifications be revoked.

Appeal Rights

The recommended revocation will become the final decision of ABIM unless you submit a request for an appeal to ABIM in writing on or before ***November 18, 2022***. If you request an appeal, your appeal would be considered by a panel designated by ABIM's Board of Directors (an "Appeal Panel"), which would hold an in-person or telephonic hearing. Appeal panels consist of three independent physicians designated by the Board of Directors, including at least one member of the Board. They have the discretion to affirm, rescind, or modify a recommended sanction, or impose an alternative sanction.

In advance of each appeal hearing, ABIM will provide you and each member of the Appeal Panel with copies of the documentary record for your sanction and appeal proceeding. In its consideration of an appeal of a recommended sanction, an Appeal Panel is not bound by any technical rules of evidence, and it considers any information timely submitted by or on behalf of the physician at any stage of the proceeding, and any other evidence that it deems appropriate.

At the hearing, you and/or your counsel may present information. Subject to the Appeal Panel's discretion, you and/or your counsel may present witnesses, provided that such witnesses were identified in your request for Appeal Panel review. ABIM's counsel may ask questions of you, your counsel, and any witnesses. The Appeal Panel, in its discretion, determines the duration of the hearing. Appeal hearings are transcribed by a professional reporter.

After reaching a decision, an Appeal Panel notifies the physician of its decision in writing. Such written decision includes the factual basis of the decision and a summary of the reason for the decision. The decision of the majority of an appeal panel is a final decision of ABIM.

If you request a hearing before the Appeal Panel, your written request must:

(i) state whether you request an in-person or telephonic hearing;

(ii) state whether you will be represented by counsel at the hearing;

(iii) identify any witnesses you intend to present on your behalf; and

(iv) include any further statement or information that you would like the Appeal Panel to consider.

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If you request a hearing, ABIM will provide notice of the members of the panel and the date, time, and if applicable, place of the hearing at least forty-five days in advance of the hearing.

Please address any request for an appeal of the recommended sanction to ABIM at **submissions@abim.org**, and kindly include your six-digit ABIM number.

Please note that a recommended revocation is not final and does not affect your current Board Certification status.

Respectfully,

Furman McDonald

Furman S. McDonald, M.D., M.P.H.
Chair, Credentials and Certification Committee

CERTIFICATE OF SERVICE

I, Adam D. Brown, certify that on May 12, 2025, I caused a copy of the foregoing Motion for Summary Judgment to be filed electronically, and the same is available for viewing and downloading from the ECF System by the following counsel of record:

Kimberly L. Russell, Esq.
Daniel Zachariah, Esq.
Kaplan Stewart Meloff Reiter & Stein, P.C.
Union Meeting Corp. Center
910 Harvest Dr.
P.O. Box 3037
Blue Bell, PA 19422
610-941-2541
krussell@kaplaw.com
dzachariah@kaplaw.com

Karyn L. White, Esq.
Pacific Justice Institute
PA/NJ Office P.O. Box 276600
Sacramento, CA 95827
609-335-4833
kwhite@pji.org

Attorneys for Plaintiff

/s/ Adam D. Brown
Adam D. Brown, Esquire